

VERMONT DEPARTMENT OF HEALTH

SHELLFISH SANITATION PROGRAM RULES

Effective Date: November 4, 2002

Purpose.

This Rule establishes the minimum requirements necessary to regulate the interstate commerce of molluscan shellfish and to establish a program to protect the public health of consumers by assuring the sale or distribution of shellfish from safe sources and assuring shellfish have not been adulterated during cultivating, harvesting, processing, shipping, or handling.

Definitions.

A. General. The definitions provided below are consistent in intent with the Shellfish Sanitation Program.

B. Definition of Terms.

- (1) **Adverse pollution condition** means a state or situation caused by meteorological, hydrological or seasonal events or point source discharges that has historically resulted in elevated fecal coliform levels in a particular growing area.
- (2) **Air gap** means the unobstructed vertical distance through the free atmosphere between the lowest opening from any pipe or faucet supplying water to a tank, plumbing fixture or other device and the flood level rim of that receptacle.
- (3) **AOAC** means the Association of Official Analytical Chemists.
- (4) **APHA** means the American Public Health Association.
- (5) **Approved** means a classification used to identify a growing area where harvest for direct marketing is allowed.
- (6) **Aquaculture** means the cultivation of seed in natural or artificial growing areas, or the cultivation of shellstock other than seed in growing areas.
- (7) **Authority** means the Vermont Department of Health which is responsible for the enforcement of this Rule.
- (8) **Assure** means to make best efforts within the reasonable limits of manpower and resources to fulfill the objectives of this Rule.
- (9) **Backflow** means the flow of water or other liquids, mixtures or substances into the distribution pipes of a potable water supply from any source or sources other than the intended source.
- (10) **Back siphonage** means the flowing back of used, contaminated or polluted water from a plumbing fixture, vessel or other source into potable water supply pipes because of negative pressure in the water supply pipes.
- (11) **Blower** means a receptacle for washing shucked shellfish which uses forced air as a means of agitation.
- (12) **Broker** means any person who is not a dealer but who arranges the packaging, shipping, sale, or distribution of molluscan shellfish without taking ownership or physical custody of the shellfish.

(13) **Certification or certify** means the issuance of a numbered certificate to a person for a particular activity or group of activities that indicates:

- (a) Permission from the Authority to conduct the activity; and
- (b) Compliance with the requirements of this Rule.

(14) **Certification number** means the unique identification number issued by the Authority to each dealer for each location. Each certification number shall consist of a one to five digit Arabic number preceded by the two letter State abbreviation and followed by a two letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with this Rule using the following terms:

- (a) Shellstock shipper (SS);
- (b) Shucker-packer (SP);
- (c) Repacker (RP);
- (d) Reshipper (RS); and
- (e) Depuration processor (DP).

(15) **Coliform group** means all of the aerobic and facultative anaerobic, gram negative, nonspore forming, rod shaped bacilli which ferment lactose broth with gas formation within 48 hours at 95° Fahrenheit (35° ± 0.5° Centigrade).

(16) **Commingle or Commingling** means the act of combining different lots of shellstock or shucked shellfish.

(17) **Compliance schedule** means a written schedule that provides a correction time period to eliminate Key and Other deficiencies.

(18) **Conditionally approved** means a classification used to identify a growing area which meets the criteria for the approved classification except under certain conditions described in a management plan.

(19) **Conditionally restricted** means a classification used to identify a growing area which meets the criteria for the restricted classification except under certain conditions described in a management plan.

(20) **Container** means any bag, sack, tote, conveyance or other receptacle used for containing shellfish for holding or transporting.

(21) **Corrosion resistant materials** means materials that maintain their original surface characteristics under normal exposure to the foods being contacted, normal use of cleaning compounds and bactericidal solutions, and other conditions of use.

(22) **Critical Control Point (CCP)** means a point, step or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated or reduced to acceptable levels.

(23) **Critical deficiency** means a condition or practice which:

- (a) Results in the production of a product that is unwholesome; or
- (b) Presents a threat to the health or safety of the consumer.

(24) **Critical limit** means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food safety hazard.

- (25) **Critical Nonconformity** means a deviation of a laboratory requirement which has the highest likelihood of adversely affecting the quality of the analytical results.
- (26) **Cross connection** means an unprotected actual or potential connection between a potable water system and any source or system containing unapproved water or a substance that is not or cannot be approved as safe and potable. Examples are bypass arrangements, jumper connection, removable sections, swivel or change over devices, or other devices through which backflow could occur.
- (27) **Cull** means to remove dead or unsafe shellstock from a lot of shellstock.
- (28) **Dealer** means a person to whom certification is issued for the activities of shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor.
- (29) **Depletion** means the removal, under the direct control of the Authority, of shellstock from a growing area classified as prohibited.
- (30) **Depuration or depurate** means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.
- (31) **Depuration Processor (DP)** means a person who harvests or receives shellstock from growing areas in the approved or conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process.
- (32) **Direct marketing** means the sale for human consumption of shellfish which:
- (a) Does not require depuration or relaying prior to sale; or
 - (b) Has been subjected to depuration or relaying activities.
- (33) **Dry storage** means the storage of shellstock out of water.
- (34) **Easily cleanable** means a surface which is:
- (a) Readily accessible; and
 - (b) Is made of such materials, has a finish, and is so fabricated that residues may be effectively removed by normal cleaning methods.
- (35) **EPA** means the United States Environmental Protection Agency.
- (36) **Facility** means a structure. For other connotations, use person or activity.
- (37) **Fecal coliform** means that portion of the coliform group which will produce gas from lactose in an EC or A-1 multiple tube procedure liquid medium within 24 (+ 2) hours in a water bath maintained at 112° Fahrenheit ($44.5^{\circ} \pm 0.2^{\circ}$ Centigrade).
- (38) **FDA** means the United States Food and Drug Administration.
- (39) **Food contact surface** means an equipment surface or utensil which normally comes into direct or indirect contact with shucked shellfish.
- (40) **Food Safety Hazard** means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.
- (41) **Geometric Mean** means the antilog (base 10) of the arithmetic mean of the sample result logarithm (base 10).
- (42) **Growing area** means any site which supports or could support the propagation of shellstock by natural or artificial means.
- (43) **HACCP** is an acronym that stands for Hazard Analysis Critical Control Point, a systematic, science-based approach used in food production as a means to

assure food safety. The concept is built upon the seven principles identified by the National Advisory Committee on Microbiological Criteria for Foods (1992).

(44) **HACCP Plan** means a written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in 21 CFR 123.6 as adopted by the Interstate Shellfish Sanitation Conference.

(45) **Harvest** means the act of removing shellstock from growing areas and its placement on or in a manmade conveyance or other means of transport.

(46) **Harvest area** means an area that contains commercial quantities of shellstock and may include aquaculture sites and facilities.

(47) **Harvester** means a person who takes shellstock by any means from a growing area.

(48) **Heat shock** means the process of subjecting shellstock to any form of heat treatment prior to shucking, including steam, hot water or dry heat, to facilitate removal of the meat from the shell without substantially altering the physical or organoleptic characteristics of the shellfish.

(49) **Importer** means any dealer who introduces molluscan shellfish into domestic commerce. An importer has ownership of the shellfish, but need not take physical custody of the shellfish.

(50) **Includes or including** means includes or including by way of illustration and not by way of limitation.

(51) **Inspection item** means one of the standard criteria listed in the NSSP Plant Inspection Form under which single or multiple observations of specific critical, key or other deficiencies can be debited. [Note: term "item" appears several places in the Rule with a larger connotation than this definition. In the section addressing the use of the inspection form, however, the Rule uses the term "inspection item" hence that is provided here as the defined term.]

(52) **Interstate Certified Shellfish Shippers List (ICSSL)** means a FDA publication of shellfish dealers, domestic and foreign, who have been certified by a state or foreign Authority as meeting the public health control measures specified in this Rule.

(53) **Interstate Shellfish Sanitation Conference (ISSC)** means the organization which consists of agencies from shellfish producing and receiving States, FDA, the shellfish industry, the National Marine Fisheries Service of the U. S. Department of Commerce, and the U. S. Environmental Protection Agency. The ISSC provides the formal structure wherein State regulatory authorities, with FDA concurrence, can establish updated guidelines and procedures for sanitary control of the shellfish industry.

(54) **Key deficiency** means a condition or practice which may result in adulterated, decomposed, misbranded or unwholesome product.

(55) **Key Nonconformity** means a deviation of a laboratory requirement which has a significant potential to adversely affect the quality of the analytical results.

(56) **Label** means any written, printed or graphic matter affixed to or appearing upon any package containing shellfish.

(57) **License** means the document issued by the Authority to a person to harvest or transport shellstock for commercial sale.

(58) **Lot of shellstock** means a single type of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area gathered by one or more harvesters.

(59) **Lot of shellstock for depuration** means shellstock harvested from a particular area during a single day's harvest and delivered to one depuration plant.

(60) **Lot of shucked shellfish** means a collection of containers of no more than one day's shucked shellfish product produced under conditions as nearly uniform as possible, and designated by a common container code or marking.

(61) **Marina** means any water area with a structure (docks, basin, floating docks, etc.) which is:

(a) Used for docking or otherwise mooring vessels; and

(b) Constructed to provide temporary or permanent docking space for more than ten boats.

(62) **Marine biotoxin** means any poisonous compound produced by marine microorganisms and accumulated by shellstock. Examples include *Alexandrium* spp. [*Protogonyaulax* species], and *Gymnodinium breve*.

(63) **May** means discretionary and is not mandatory or required.

(64) **Milliliter** (ml) means a unit of measurement equal to the 0.001 portion of a liter.

(65) **Monoculture** means the culture of a single bivalve species.

(66) **MPN (Most Probable Number)** means a statistical estimate of the number of bacteria per unit volume and is determined from the number of positive results in a series of fermentation tubes.

(67) **NSSP** means the cooperative State-FDA-Industry program for the sanitary control of shellfish that is adequate to insure that the shellfish produced in accordance with these guidelines will be safe and sanitary.

(68) **Open water aquaculture** means the cultivation of bivalve shellfish in natural shellfish growing areas.

(69) **Other deficiency** means a condition or practice that is not defined as critical or key and is not in accordance with the requirements of this Rule.

(70) Other **Nonconformity** means a deviation of a laboratory requirement which does not normally compromise the quality of the analytical results, but generally serves to enhance the overall operation of the laboratory.

(71) **Person** means any individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind, and any partnership, association, corporation or other entity. Person includes the federal government, the State, and any other public or private entity.

(72) **Point source** means any discernible, confined and discrete conveyance including any pipe, ditch, channel, tunnel or conduit that carries pollution.

(73) **Poisonous or deleterious substance** means a toxic substance occurring naturally or added to the environment for which a regulatory tolerance limit or action level has been established in shellfish to protect public health.

(74) **Polyculture** means the cultivation of:

(a) Two or more species of shellfish; or

(b) Shellfish with other species in a common environment.

(75) **Potable water** means a water supply which meets the requirements of the Safe Drinking Water Act, as administered by the EPA, and any applicable state or local requirements.

(76) **Principal display panel** means that part of a label that is most likely to be displayed, presented, shown or examined under customary conditions of retail sale.

(77) **Process batch** means a quantity of shellstock used to fill each separate tank or a series of tanks supplied by a single process water system for a specified depuration cycle in a depuration activity.

(78) **Process water** means the water used in the scheduled depuration process.

(79) **Prohibited** means a classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion or gathering of seed for aquaculture, is not permitted.

(80) **Relay** means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(81) **Remote status** means a designation applied to a shellfish growing area that has no human habitation and is not impacted by any actual or potential pollution sources.

(82) **Repacker (RP)** means any person, other than the original certified shucker-packer, who repackages shucked shellfish into other containers.

(83) **Repacking Shellstock** means the practice of removing shellstock from containers and placing it into other containers.

(84) **Reshipper (RS)** means a person who purchases shucked shellfish or shellstock from dealers and sells the product without repacking or relabeling to other dealers, wholesalers, or retailers.

(85) **Restricted** means a classification used to identify a growing area where harvesting shall be by special license and the shellstock, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration.

(86) **Safe materials** means articles manufactured from or composed of materials that may not reasonably be expected to, directly or indirectly, become a component of or otherwise adversely affect the characteristics of any food.

(87) **Sanitation control record** means records that document the monitoring of sanitation practices and conditions during processing.

(88) **Sanitary survey** means the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on the water quality in a shellfish growing area.

(89) **Sanitize** means to adequately treat food contact surfaces by a process that is effective in:

(a) Destroying vegetative cells of microorganisms of public health significance;

(b) Substantially reducing the numbers of other undesirable microorganisms;

and

(c) Not adversely affecting the product or its safety for the consumer.

(90) **Seed** means shellstock which is less than market size.

(91) **Shall** means mandatory and required.

(92) **Shellfish** means all species of:

(a) Oysters, clams or mussels, whether:

(i) Shucked or in the shell;

(ii) Fresh or frozen; and

(iii) Whole or in part; and

(b) Scallops in any form, except when the final product form is the adductor muscle only.

(93) **Shellstock** means live molluscan shellfish in the shell.

(94) **Shellstock packing** means the process of placing shellstock into containers for introduction into commerce.

(95) **Shellstock Shipper (SS)** means a dealer who grows, harvests, buys, or repacks and sells shellstock. They are not authorized to shuck shellfish or to repack shucked shellfish. A shellstock shipper may also ship shucked shellfish.

(96) **Should** means recommended but is not required.

(97) **Shucker-Packer (SP)** means a person who shucks and packs shellfish. A shucker-packer may act as a shellstock shipper or reshipper or may repack shellfish originating from other certified dealers.

(98) **Standardization** means a process in which applicable staff from the FDA and the Authority conduct evaluations using standard criteria in a uniform manner.

(99) **State shellfish standardization inspector** means a person that has successfully completed the FDA standardization training course (or one deemed acceptable by the FDA) and the field evaluation phase of shellfish plant inspection with either an FDA standardization officer or a state standardization officer.

(100) **State shellfish standardization officer** means a person that has successfully completed the FDA standardization-training course and the field evaluation phase of shellfish plant inspection with a FDA standardization officer.

(101) **Swing deficiency** means a deficiency noted on the NSSP Standardized Shellfish Processing Plant Inspection Form which, depending upon the severity and circumstances, can be either a "Critical" or a "Key" deficiency.

(102) **Transaction record** means the form or forms used to document each purchase or sale of shellfish at the wholesale level, and includes shellfish harvest and sales records, ledgers, purchase records, invoices and bills of lading.

(103) **Wet storage** means the temporary storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater.

VERMONT DEPARTMENT OF HEALTH

SHELLFISH SANITATION RULE

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I. SHELLFISH SANITATION PROGRAM

Requirements for the Authority.

@.01 Administration.

A. Scope. The Authority shall establish a statewide shellfish safety and sanitation program to regulate:

- (1) The classification of shellfish growing areas;
- (2) The harvesting of shellfish;
- (3) Shellfish processing procedures and facilities;
- (4) Product labeling;
- (5) Storage, handling and packing;
- (6) Shellfish shipment in interstate commerce;
- (7) Shellfish dealers; and
- (8) Bivalve aquaculture.

B. Records. The Authority shall maintain records to demonstrate the effective administration of a statewide shellfish safety and sanitation program. These records shall be maintained in a central file and made available to any interested person upon request, consistent with appropriate state and federal law.

C. Shared Responsibilities. If more than one agency is involved in the administration of the statewide shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities.

D. Administrative Procedures. The Authority shall have administrative procedures sufficient to:

- (1) Regulate shellfish harvesting, sale, or shipment; and
- (2) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the state from which the shellstock are harvested or landed, unless the Authority has a memorandum of understanding with the Authority in another State to allow dealers from its state to purchase the shellstock.
- (3) Detain, condemn, seize, and embargo shellfish.
- (4) Assure compliance with Shellfish Plant Inspection Standardization.

E. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness. The Authority shall have procedures for investigating incidents of shellfish borne disease.

F. Commingling.

- (1) Except for any shellstock included in the Authority's commingling plan, the Authority shall not permit the commingling of shellstock.
- (2) If the Authority permits shellstock commingling, the Authority shall develop a commingling management plan. The plan shall:
 - (a) Minimize the commingling dates of harvest and growing areas;
 - (b) Define a primary dealer;
 - (c) Limit the practice of commingling to primary dealers;
 - (d) Limit commingling to shellstock harvested from specific growing areas within the State as identified by the Authority and purchased directly from

harvesters; and

(e) Define how the commingled shellstock will be identified.

@.02 Dealer Certification.

A. General

(1) A person requesting certification shall be subject to a comprehensive, onsite inspection and meet the criteria in §B. or §C., as appropriate. The plant inspection shall be conducted by the state shellfish standardization inspector, using the appropriate inspection form, within the 120-day period immediately prior to the issuance or renewal of the certification.

(2) Certification shall be given only to persons who meet the requirements established for certification.

(3) All certifications shall expire annually. The month selected for certification expiration shall be at the discretion of the Authority.

(4) The Authority shall issue only one certification number to a dealer for a location. A person or dealer may obtain more than one certification if each business is:

(a) Maintained as a separate entity; and

(b) Is not found at the same location.

(5) The Authority may permit separate certified dealers to share a facility.

(6) The certification number issued to each dealer by the Authority shall be unique.

(7) Adequate records documenting each dealer's compliance with certification requirements shall be maintained for at least three years. These records shall include:

(a) Inspection reports of dealers;

(b) Notification letters and enforcement actions;

(c) Shellfish sample results and follow-up actions taken;

(d) Records of complaints or inquiries and follow-up actions taken; and

(e) Administrative hearing transcripts and records.

B. Initial Certification.

(1) Initial certification shall be given only to persons who meet the following standards for certification:

(a) No critical deficiencies:

(b) Not more than 2 key deficiencies; and

(c) Not more than 3 other deficiencies.

(2) The initial certification shall include a compliance schedule to correct the deficiencies if necessary.

C. Renewal of Certification.

(1) A dealer shall make application for certification renewal annually at the time specified by the Authority.

(2) The Authority shall not renew the certification for any dealer until the dealer has:

(a) Eliminated any critical deficiencies:

(b) Agreed to a compliance schedule which carries forward into the next certification period no more than 1 key and 2 other deficiencies identified in previous inspections; and

- (c) Addressed any new key or other deficiencies in a new or revised compliance schedule; and
 - (d) Met the requirements of §A.(2).
- D. Revocation or Suspension of Certification.
 - (1) The Authority shall not allow any dealer whose certification has been suspended or revoked under §H. to deal in shellfish.
 - (2) The Authority shall not issue certification to a dealer whose certification has been suspended or revoked to deal in shellfish until the dealer meets the requirements for initial certification.
- E. Interstate Certified Shellfish Shippers List (ICSSL).
 - (1) When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. The notice shall be in the format of FDA Form 3038.
 - (2) The Authority shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate is:
 - (a) Suspended; or
 - (b) Revoked.
- F. Inspections.
 - (1) After any person is certified, the Authority shall make unannounced inspections of the dealer's facilities:
 - (a) During periods of activity; and
 - (b) At the following minimum frequencies:
 - (i) Within 30 days of beginning activities if the dealer was certified on the basis of a pre-operational inspection;
 - (ii) At least monthly for dealer facilities certified as depuration processors;
 - (iii) At least quarterly for dealer's activities certified as shucker-packer or repacker; and
 - (iv) At least every 6 months for other dealer activities.
 - (2) The Authority shall provide a copy of the completed inspection form to the person in-charge at the dealer's operation at the time of inspection. The inspection form shall contain a listing of deficiencies by area in the operation and inspection item with corresponding citations to this Model Rule.
- G. Performance Based Inspection Program (PIP).
 - (1) The Authority may institute a performance based inspection program for any dealer who meets the requirements of this section.
 - (2) The minimum frequency of inspection under a PIP shall be no less than one inspection per certification period. The recertification inspection may qualify as the required minimum inspection frequency.
 - (3) To be eligible for a PIP, the dealer shall have demonstrated a history of satisfactory compliance for the previous three-year period. The three-year demonstration shall include:
 - (a) Full compliance with the minimum inspection frequency shown under §F.;
 - (b) Recertification of the dealer by the Authority;
 - (c) Verification that no critical deficiencies, no more than one key deficiency and no more than two other deficiencies have occurred in any one inspection;

- (d) Correction of all identified deficiencies in accordance with the compliance schedule approved by the Authority; and
 - (e) No repetition of the identified deficiencies.
- H. Enforcement.
- (1) General.
 - (a) The Authority shall use any combination of administrative hearings, fines, certification cancellations, temporary suspension of operating licenses, embargoes, product condemnations or product seizures to accomplish the implementation of this Rule.
 - (b) When a dealer has failed to meet the compliance schedule, the Authority shall:
 - (i) Consider whether it is appropriate to revise the compliance schedule, suspend or revoke the dealer's certification, or seek other administrative remedies; and
 - (ii) Document why an option was selected.
 - (2) Actions Triggered by Inspections.
 - (a) When any inspection detects a critical deficiency:
 - (i) The deficiency shall be corrected during that inspection; or
 - (ii) The dealer must cease production affected by the deficiency.
 - (b) When the dealer fails to comply with (a) above, the Authority shall immediately begin actions to suspend or revoke the dealer's certification.
 - (c) Product affected by a critical deficiency shall be controlled to prevent contaminated or adulterated product from reaching consumers. When necessary the Authority shall:
 - (i) Detain or seize any undistributed lots of shellfish that may have been adulterated;
 - (ii) Initiate a recall of any distributed shellfish; and
 - (iii) Immediately notify the enforcement officials for FDA and any other Authorities where the product was distributed.
 - (d) When any inspection detects any key or other deficiencies not already covered in a compliance schedule, the Authority, working with the dealer, shall develop a compliance schedule to correct the new key or other deficiencies.
 - (e) When any inspection detects four or more new key deficiencies, the Authority shall consider the following options and document the reasons for the selection of a particular option:
 - (i) Revise the existing compliance schedule;
 - (ii) Suspend or revoke the dealer's certification; or
 - (iii) Seek other administrative remedies.

II. RISK ASSESSMENT AND RISK MANAGEMENT

Requirements for the Authority.

@.01 Outbreaks of Shellfish-Related Illness.

A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one or more persons in the case of PSP), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:

- (1) Each consumer's food history;
- (2) Shellfish handling practices by the consumer and/ or retailer;
- (3) Whether the disease has the potential or is known to be transmitted by shellfish;
- (4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.

NOTE: For additional guidance refer to the International Association of Milk, Food, and Environmental Sanitarians' *Procedures to Investigate Food Borne Illness*.

B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.

C. When the investigation outlined in §.02B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:

- (1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;
- (2) Notify receiving states and the FDA that a potential health risk is associated with shellfish harvested from the implicated growing area;
- (3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and
- (4) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 Code of Federal Regulations Part 7.

D. When the investigation outlined in §.02B demonstrates that the illnesses are related to post-harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:

- (1) Notify receiving states of the problem; and
- (2) Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7.

E. When the investigation outlined in §.02B. cannot be completed within 24 hours, the Authority shall:

- (1) Follow the closure procedure outlined in § 01C; and
- (2) If the investigation does not indicate a growing area problem, the area shall be immediately reopened and product recall terminated.

F. Upon closing an implicated area for problems other than natural occurring pathogens and/ or biotoxins the Authority shall review the growing area classification and determine if a growing area classification problem exists. The review shall include at a minimum:

- (1) A review of the growing area classification file records;
- (2) A field review of existing pollution sources;
- (3) A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection

systems; and

(4) Examination of water quality subsequent to the illness outbreak.

G. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/ or biotoxins, the Authority shall:

(1) Follow an existing marine biotoxin contingency plan, if appropriate.

(2) Collect and analyze samples relevant to the investigation, if appropriate.

(3) Keep the area closed until it has been determined that levels of naturally occurring pathogens and/ or biotoxins are not a public health concern.

H. When the growing area is determined the problem, the Authority shall:

(1) Place the growing area in the closed status until:

(a) The Authority verifies that the area is properly classified, using current data, in compliance with the Authority's Rules; or

(b) Shellfish from the growing area are confirmed as the cause of illness but it has been determined that the event which caused the contamination no longer exists;

(2) Keep the area closed for a minimum of 21 days if the illness is consistent with viral etiology; and

(3) Develop a written report summarizing the findings of the investigation and actions taken.

I. Whenever the Authority initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall.

The Authority will monitor the progress and success of the recall. The Authority initiating the recall will immediately notify the FDA and the Authorities in other states involved in the recall. Each Authority involved in a recall will issue public warnings if necessary to protect public health. The FDA will not normally audit or issue public warnings about such a recall. If the FDA determined that the Authority in any state involved in the recall fails to implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate.

@.02 Presence of Human Pathogens in Shellfish Meats.

A. Finding. Upon determination that human pathogens are present in shellfish meats, the Authority shall investigate the harvesting, the distribution, and the processing of the shellfish.

B. Growing Area Investigation.

(1) The Authority shall review the following factors:

(a) The documentation to trace the shellfish to its source;

(b) The classification assigned to the growing area and whether the sanitary survey data supporting that classification is current; and

(c) The probability of illegal harvesting from areas classified as restricted or prohibited, or in the closed status.

(2) The Authority shall take no further action when the Authority determines that:

(a) The growing area is properly classified;

(b) No illegal harvesting is taking place; and

(c) There is no reason to believe that the growing area is the source of the pathogens.

- (3) When the Authority determines that the growing area is not properly classified, the Authority shall take immediate action to:
 - (a) Change the existing classification to the correct classification; or
 - (b) Close the growing area until the correct classification can be determined.
- C. Distribution and Processing Investigation.
 - (1) The Authority shall evaluate the distribution and processing of the shellfish. This investigation may include collection of additional meat samples.
 - (2) The Authority shall take no further action when the Authority determines that there is no reason to believe a problem exists in the distribution or processing of the shellfish.
 - (3) When the Authority determines that a problem exists in the distribution or processing of the shellfish, the Authority shall take immediate steps to correct the problem.
- D. Risk Management and Tolerance Levels.
 - (1) Pathogen Present. When a growing area continues to demonstrate the presence of human pathogen isolates in shellfish meats in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification for an area.
 - (2) Established Tolerance Levels.
 - (a) When the established tolerance level for a particular pathogen isolate is not exceeded, the Authority:
 - (i) Shall maintain a written summary of its finding and the data supporting its finding in its central file; and
 - (ii) May leave the growing area in its present classification.
 - (b) When the established tolerance level for a particular pathogen isolate is known and there are no known outbreaks of shellfish associated disease caused by that pathogen in a particular growing area, the Authority shall:
 - (i) Leave the area in the open status of its classification when the tolerance level is not exceeded; and
 - (ii) Place the area in the closed status of its classification when the tolerance level is exceeded.
 - (c) When the tolerance level is exceeded, the Authority may:
 - (i) Maintain the growing area in the closed status of its current classification;
 - (ii) Reclassify the growing area to the restricted or prohibited classification; or
 - (iii) Reclassify the growing area to the conditionally restricted classification and establish a management plan.
 - (d) Any management plan based on shellstock exceeding established tolerance levels shall:
 - (i) Meet all appropriate requirements for a management plan for the conditionally approved or conditionally restricted classification;
 - (ii) Specify the additional criteria associated with the particular pathogen isolate that the growing area must meet to be in the open status of its classification;
 - (iii) Document the scientific basis for the additional criteria;

- (iv) Provide for periodic retesting of the shellfish meats; and
 - (v) Provide for the growing area to be placed in the closed status if the criteria are exceeded.
- (3) Established Tolerance Levels Not Known.
 - (a) When an established tolerance level does not exist for the particular pathogen isolated, the Authority shall assess the public health significance of the levels of the pathogen found in the growing area shellfish meats. The Authority may consider FDA recommended action levels or levels of concern in this determination. When the Authority determines that:
 - (i) The levels are acceptable, the growing area shall remain in the open status of its classification; or
 - (ii) The levels are unacceptable, the growing area shall be placed in the closed status of its classification.
 - (b) If a growing area is placed in the closed status, the Authority may elect to:
 - (i) Maintain that status indefinitely;
 - (ii) Reclassify the area to the restricted or prohibited classification; or
 - (iii) Reclassify the area to the conditionally restricted classification and establish a management plan. The management plan shall meet the requirements of §D.(2)(d).

@.03 Presence of Toxic Substances in Shellfish Meats.

A. Upon determination that toxic substances, including heavy metals, chlorinated hydrocarbons, and natural toxins are present in levels of public health significance in shellfish meats, the Authority shall investigate the harvesting, distribution, and processing of shellfish and take necessary corrective action in accordance with the procedures described in §.02.

B. When a growing area continues to demonstrate the presence of toxic substances in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification of the area. The risk assessment and subsequent risk management shall follow the procedures outlined in §.02D., Risk Management and Tolerance Levels.

III. LABORATORY

Requirements for the Authority.

@.01 Quality Assurance.

A. NSSP Conformance Required. All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA or FDA certified State Shellfish Laboratory Evaluation Officer (LEO) in accordance with the requirements established under the NSSP.

B. State Program Requirements. The Authority shall assure that all samples are collected, maintained, transported and analyzed in a manner that assures the validity of the analytical results. The Authority shall:

- (1) Require laboratories to develop a written quality assurance plan that:

- (a) Describes the organization and management structure of the laboratory;
 - (b) Describes the laboratory staff training program ensuring that all laboratory personnel are qualified, properly trained, and supervised;
 - (c) Describes all procedures and methods used to collect, maintain, transport and analyze samples;
 - (d) Describes quality control measures, their frequency and tolerance limits, for determining equipment performance;
 - (e) Requires maintenance of records of analytical performance, quality control results, and equipment maintenance and calibration;
 - (f) Provides a quality assessment program to demonstrate laboratory and analyst competence. At a minimum this program must include triennial onsite laboratory evaluations conducted by either FDA laboratory evaluation officers or FDA certified state laboratory evaluation officers, and annual internal laboratory audits. For microbiological laboratories, participation in the annual FDA sponsored proficiency test programs is also required; and
 - (g) Requires corrective action for any deficiencies found in the laboratory quality assurance program.
- (2) Require laboratories to implement their quality assurance plan;
 - (3) Ensure that the laboratory has appropriate facilities and resources to effectively manage the workload;
 - (4) Require triennial or more frequent evaluations of all laboratories which conduct both microbial and marine biotoxin and analyses used to officially support the state shellfish program; and
 - (5) Require a laboratory to be re-evaluated when any major changes in personnel, workload, or facilities occur and when a laboratory is found in nonconformance.
- C. An FDA certified State Shellfish Laboratory Officer may evaluate laboratories in a different State under a memorandum of understanding agreement between the States and FDA. The agreement shall be consistent with NSSP requirements.
- D. Laboratory Evaluation.
- (1) Laboratory Status. Continued acceptance of analytical data in support of the NSSP by the Authority from any operating laboratory is contingent upon the laboratory being found to conform or provisionally conform to NSSP requirements as determined in their most recent laboratory evaluation using the NSSP standardized laboratory evaluation criteria listed in Section IV Guidance Documents A. 12.
 - (a) Conforms. In order to achieve or maintain its conforms status, a laboratory shall meet the following requirements under the NSSP standardized laboratory evaluation criteria:
 - (i) No critical nonconformities have been identified;
 - (ii) Not more than 12 key nonconformities for microbiological or 4 for paralytic shellfish poisoning component have been identified;
 - (iii) Not more than 17 critical, key, and other nonconformities in total or 9 for paralytic shellfish poisoning component have been identified (not to exceed the critical and key criteria); and

(iv) No repeat key nonconformities have been identified in consecutive evaluations.

(b) Provisionally Conforms. In order to achieve provisionally conforming status, a laboratory shall meet the following requirements under the NSSP standardized microbiological laboratory evaluation criteria:

(i) Not more than 3 critical nonconformities for the microbiological or 1 for paralytical shellfish poisoning component have been identified;

(ii) Not more than 12 key nonconformities for the microbiological or 4 for paralytical shellfish poisoning component have been identified; and

(iii) Not more than one repeat Key nonconformity has been identified in consecutive evaluations.

(c) Nonconformance. When a laboratory exceeds the following criteria, the laboratory shall be determined to be in nonconformance:

(i) More than 3 critical nonconformities for the microbiological or 1 for paralytic shellfish poisoning component have been identified;

(ii) More than 12 key nonconformities for the microbiological or 4 for paralytic shellfish poisoning component have been identified; and

(iii) More than 17 critical, key, and other nonconformities for microbiological or 9 for paralytic shellfish poisoning component have been identified; or

(iv) One or more repeat critical or two or more key nonconformities have been identified in consecutive evaluations.

E. Time Limit on Laboratory Status.

(1) Conforming Status. A laboratory in conforming status may operate for up to 90 days during which the laboratory must be actively working on an FDA or FDA certified State Shellfish LEO approved action plan to maintain its conforming status. After this period, the laboratory shall be assigned a nonconforming status if all key deficiencies have not been successfully corrected.

(2) Provisionally Conforming Status. A laboratory in the provisionally conforming status may operate for up to 60 days during which the laboratory must be actively working on a FDA approved action plan that will bring the laboratory into the NSSP conforms status. After this period, the laboratory shall be assigned a status as:

(a) Conforms if all the critical and key nonconformities have been successfully corrected; or

(b) Nonconforming if any critical or key nonconformities have not been successfully corrected.

(3) Nonconformance. Upon determination of nonconforming status, data generated from the laboratory shall not be used in support of the NSSP. If the laboratory wishes to attain conforming status, the laboratory must immediately implement an FDA or FDA certified State Shellfish LEO approved action plan and has up to 30 days to demonstrate successful correction of all critical and key deficiencies. After this period, an onsite re-evaluation should be conducted. Upon re-evaluation, only a status of conforming shall allow data to be accepted in support of the NSSP.

F. Laboratory Services for Depuration Processors. For any laboratory providing services for the quality assurance program (e. g. water quality) including end product testing of any depuration processor, the Authority shall:

(1) Require the annual inspection of the laboratory in accordance with @.01 and @.02 of this Chapter.

(2) Require the laboratory to retain its records for a minimum of the previous two years.

@.02 Methods.

A. Microbiological. Methods, practices and procedures for the analyses of shellfish and shellfish growing or harvest waters shall be the methods required by the National Shellfish Sanitation Program.

B. Chemical and Physical.

(1) Methods for the analysis of shellfish and shellfish growing or harvest waters shall:

(a) Be the current AOAC or APHA method for all physical and chemical measurements; and

(b) Express results of all chemical and physical measurements in standard units, and not instrument readings.

(2) When an AOAC or APHA method is not available, EPA methods may be used.

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:

(1) The current AOAC and APHA methods used in bioassay for paralytic shellfish poisoning toxins; and

(2) The current APHA method used in bioassay for *Gymnodinium breve* toxins.

IV. WET STORAGE IN APPROVED AND CONDITIONALLY APPROVED GROWING AREAS

Requirements for the Dealer.

.01 Source of Shellstock.

A. The dealer shall wet store shellstock harvested only from areas classified as approved, conditionally approved, or taken from a certified depuration facility following successful completion of the depuration process.

B. Shellstock shall be harvested, identified and shipped to the wet storage operation in accordance with the requirements of Chapters V and VI.

.02 General.

A. Wet storage may be used to store, condition, remove sand or to add salt to shellstock.

B. Wet storage of depurated product shall occur only within the facility in which it was depurated.

C. Wet storage shall be practiced only by a dealer in strict compliance with the provisions in the written approval for the wet storage activity given by the Authority.

D. While awaiting placement in a wet storage operation, shellstock shall be protected from physical, chemical or thermal conditions which may compromise the shellstock's survival, quality or activity during wet storage.

E. Conditions and water quality during wet storage shall be sufficient to minimize the potential for compromising the sanitary quality of the shellstock during storage.

F. For the purpose of certification, each wet storage site or operation shall be evaluated annually. The evaluation shall include an inspection of the near shore storage site and floats, or the wet storage operation.

G. Shellstock from a wet storage operation shall be harvested, identified and shipped according to the requirements of Chapters V, VI and VII. Any dealer who wet stores shellstock from another state and ships the shellstock as a product of the state where the shellstock was wet stored shall be required to:

(1) Have an operational plan approved by the Authority which describes how this labeling change will be employed in assuring that shellstock can be traced to its source; and

(2) Meet the requirements of Chapter VI.

H. When the product from wet storage was depurated prior to wet storage, the shellstock shall:

(1) Include the dates of wet storage on the labels or tags.

I. The wet storage operator shall keep complete and accurate records to enable a lot of shellstock to be traced back to the wet storage location. The records shall be maintained for at least:

(1) 90 days from the date of removal of the shellstock from wet storage; and

(2) 120 days from the date of removal of the shellstock from wet storage where the state of origin labeling is changed under §G. 2.

.03 Wet Storage Sites.

A. Near shore waters used for wet storage in containers and floats shall meet the requirements for classification as approved or conditionally approved while shellstock is being held in storage. Areas classified as conditionally approved may be used only when in the open status. When an area classified as conditionally approved is placed in a status other than its open status, any shellstock in wet storage in that area shall be:

(1) Subjected to relaying or depuration prior to human consumption; or

(2) Held in the wet storage site until the area is returned to the open status.

B. The near shore site evaluation shall include:

(1) The sanitary survey of the near shore storage site, with special consideration of potential intermittent sources of pollution;

(2) The location of near shore storage sites and floats; and

(3) The examination of the construction of shellstock containers, if used, to ensure the free flow of water to all shellstock.

C. Different lots of shellstock shall not be commingled in wet storage. If more than one lot of shellstock is held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

V. CONTROL OF SHELLFISH HARVESTING

Requirements for Harvesters.

.02 Shellstock Harvesting and Handling.

D. Shellstock Washing.

- (1) Shellstock shall be washed reasonably free of bottom sediments as soon after harvesting as practicable.
- (2) The harvester shall be primarily responsible for washing shellstock.
- (3) If shellstock washing is not feasible at the time of harvest, the dealer shall assume this responsibility.
- (4) Water used for shellstock washing shall be obtained from:
 - (a) A potable water source; or
 - (b) A growing area in the:
 - (i) Approved classification; or
 - (ii) In the open status of the conditionally approved classification.
- (5) If the harvester or dealer elects to use tanks or a recirculating water system to wash shellstock, the shellstock washing activity shall be constructed, operated, and maintained in accordance with Chapter VIII.02.A.(3) and Chapter X.02.A.(3).

E. Shellstock Identification.

- (1) Each harvester shall affix a tag to each container of shellstock which shall be in place while the shellstock is being transported to a dealer.
- (2) If the shellstock was harvested at more than one location, each container shall be tagged at its growing area.
- (3) When the harvester is also the dealer, the harvester has the option to tag the shellfish with a harvester's tag or a dealer's tag meeting the requirements outlined in §VII. 05.
- (4) The harvester's tags shall:
 - (a) Be durable, waterproof and sanctioned by the Authority prior to use; and
 - (b) Be at least 2 5/8 inches x 5 ¼ inches (6.7 x 13.3 cm) in size.
- (5) The harvester's tag shall contain the following indelible, legible information in the order specified below:
 - (a) The harvesters' identification number as assigned by the Authority;
 - (b) The date of harvest;
 - (c) The most precise identification of the harvest location or aquaculture site as is practicable, including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).
 - (d) The type and quantity of shellstock; and
 - (e) The following statement in bold capitalized type on each tag

"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."

(6) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in §.02E.

(7) Bulk Tagging of a Lot of Shellstock During Transport from Harvest Area to the Dealer Facilities.

(a) When shellstock are harvested from one harvest area on a single day, multiple containers may be utilized on a wrapped pallet, in a tote, in a net brailer, or other container and the unit tagged with a single tag in accordance with the requirements of §.02E.

(b) In addition to the information required in §.02E the unit tag shall also include:

(i) A statement that "All shellstock containers in this lot have the same harvest data and area of harvest"; and

(ii) Number of individual containers in the unit.

(8) Bulk Sale of Shellstock. If shellstock are sold in bulk, the harvester or dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in §.02E. with the addition of the name of the consignee.

.03 Shellstock Temperature Control.

OPTION 3

A. For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering temperature of the shellstock to, and will maintain it at, 50° Fahrenheit (10° Centigrade) or less.

B. Ocean Quahogs (*Arctica islandia*) and surf clams (*Spisula solidissima*) are exempted from this temperature control plan when these products are intended for thermal processing.

C. Temperature determinations for application in the time-temperature matrix below shall be based on average monthly maximum air temperatures for defined regions within the state. The average monthly maximum air temperature for each region shall be established by determining the mean daily high temperature for the month in each of the previous five years as reported by the National Weather Service, and then averaging the five resulting temperatures. Ocean Quahogs (*Arctica islandia*) are exempted from this temperature control plan.

| ACTION LEVEL | AVERAGE MONTHLY MAXIMUM AIR TEMPERATURE | MAXIMUM HOURS FROM HARVEST TO TEMPERATURE CONTROL |
|---------------------|--|--|
| LEVEL 1 | <66° F (18° C) | 36 hours |
| LEVEL 2 | 66° F -80° F (19° C -27° C) | 24 hours |
| LEVEL 3 | > 81° F (> 27° C) | 20 hours |

VI. TRANSPORTATION

Requirements for the Authority.

@.01 General.

- A. The Authority shall apply these requirements to all shellfish shipped in interstate commerce.
- B. The Authority shall assure that:
 - (1) Shellfish are transported and maintained in accordance with the requirements of this Chapter; and
 - (2) Shellfish shipments originate from a dealer.
- C. The Authority shall use the temperatures included in the sections below entitled @.02 Shipment Acceptability, @.03 Shipment Rejection, and @.04 Bacteriological Examination of Shellfish Shipments as the initial basis for taking regulatory action against any shellfish shipment in interstate commerce.
- D. If an interstate shipment of shellfish is monitored, the monitoring shall take place within 24 hours of the shellfish entering the State.

@.02 Shipment Acceptability. Shellfish shipments shall be considered acceptable when:

- A. Shipments are properly identified with tags and shipping documents;
- B. Shellstock is alive and cooled to an internal shellstock body temperature of 50° Fahrenheit (10° Centigrade) or less;
- C. Shucked shellfish is cooled to a temperature of 45° Fahrenheit (7.2° Centigrade) or less; and
- D. The time-temperature indicating device shows that the ambient air temperature has exceeded 45° Fahrenheit (7.2° Centigrade) but the shellstock internal body temperature is 50° Fahrenheit (10° Centigrade) or less; and
- E. All other conditions of shipment in this Chapter are met.

@.03 Shipment Rejection.

- A. Shellfish shall be rejected when:
 - (1) Shellfish are not properly identified with tags or shipping documents;
 - (2) The internal shellstock body temperature exceeds 60° Fahrenheit (15.6° Centigrade) unless the harvest initiation time can be documented and indicates that the time from harvest has not exceeded the requirements in Chapter V. §.03;
 - (3) Shucked shellfish exceeds 50° Fahrenheit (10° Centigrade); or
 - (4) The Authority determines that the product is unwholesome or unsafe for human consumption.
- B. The Authority shall notify the shipping dealer, the receiving dealer, and the Authority in the State where the shipment originated of the shipment's rejection.

@.04 Bacteriological Examination of Shellfish Shipments.

If the Authority chooses to sample, the following protocol shall be used.

- A. Bacteriological samples of any shellfish taken for the purpose of rejection of shipments from out-of-state dealers shall be collected within twenty-four hours of the shellfish entering Vermont.
- B. Bacteriological examination shall be made of the shellfish shipment if:
 - (1) The internal body temperature of the shellstock exceeds 50° Fahrenheit (10 Centigrade) and is less than or equal to 60° Fahrenheit (15.6° Centigrade) unless the harvest initiation time can be documented and indicates that the time from harvest has not exceeded the requirements in Chapter V. §.03;
 - (2) The shucked shellfish temperature exceeds 45° Fahrenheit (7.2° Centigrade) and is less than or equal to 50° Fahrenheit (10° Centigrade);
 - (3) The shipping time exceeds four hours and there is no temperature recording device or the recording device is inoperative; or
 - (4) The Authority determines it is necessary.

Requirements for the Harvester/ Dealer.

01. Trucks or Other Vehicles Used to Transport Shellstock to the Original Dealer.

- A. The harvester, or dealer who transports shellstock from the harvester to the original dealer, shall assure that all trucks used to transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition.
- B. Storage bins on trucks or other vehicles used in the transport of shellstock for direct marketing shall be:
 - (1) Kept clean with potable water or water from an approved area or conditionally approved area in the open status; and
 - (2) Provided with effective drainage.
- C. Shellstock shall be transported in adequately refrigerated trucks when the shellstock have been previously refrigerated or when ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur.
- D. Prechilling trucks or other vehicles shall be required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.
- E. When mechanical refrigeration units are used, the units shall be:
 - (1) Equipped with automatic controls; and
 - (2) Capable of maintaining the ambient air temperature in the storage area at temperatures of 45° Fahrenheit (7.2° Centigrade) or less.
- F. Any ice used to cool shellstock during transport shall meet the requirements of Chapter VIII. 02A.(2).
- G. Cats, dogs, and other animals shall not be allowed in any part of the truck or other vehicle where shellstock is stored.

02. Receiving Shellfish

- A. The dealer shall reject or discard any shellfish shipments which:
 - (1) Do not originate from a licensed harvester or dealer; and/ or
 - (2) Are unwholesome, inadequately protected, or whose source cannot be identified.
- B. Transportation agents or common carriers used by a dealer are not required to be certified.

C. The dealer shall:

- (1) Inspect incoming shellfish shipments to assure that the shipments are received under the conditions required in this Chapter;
- (2) Ensure that shellstock are not permitted to remain without ice, mechanical refrigeration, or other approved means of lowering the internal body temperature of the shellstock to, or maintaining it at, 50° Fahrenheit (10° Centigrade) or less for more than 2 hours at points of transfer such as loading docks;
- (3) Ensure that shucked shellfish are not permitted to remain without ice, mechanical refrigeration, or other approved means of maintaining shellfish temperature at 45° Fahrenheit (7.2° Centigrade) or less; and
- (4) Ensure that frozen shellfish remain frozen.

.03 Transportation Containers.

- A. All containers used to transport shellstock shall be:
 - (1) Constructed to allow for easy cleaning; and
 - (2) Operated and maintained to prevent product contamination.
- B. All containers shall be cleaned with:
 - (1) Potable water; and
 - (2) Detergents, sanitizers, and other supplies acceptable for food contact surfaces.

.04 Cargo Protection From Cross Contamination.

- A. General. All containers used for storing shellfish shall be clean and fabricated from safe materials.
- B. Shellfish Cargo Only.
 - (1) The entire cargo shall consist of shellfish products only.
 - (2) Except for bulk shipments, shellstock shipments shall be shipped on pallets.
 - (3) If the conveyance does not have a channeled floor, pallets shall be used for all shellfish.
- C. Mixed Cargos. Shellfish shall be shipped as part of a mixed cargo of seafood or other food product only when:
 - (1) Shellfish products are protected from contamination by the other cargo;
 - (2) All cargo is placed on pallets; and
 - (3) No other cargo is placed on or above the shellfish unless all cargo is packed in sealed, crush resistant, waterproof containers.
- D. Ice. Any ice used to cool shellfish shall meet the requirements of Chapter VIII. 02A.(2).

.05 Shipping Times.

- A. Shipping Time is No More Than Four Hours.
 - (1) When the shipping time is four hours or less, the dealer shall ship all shellfish:
 - (a) Well iced; or
 - (b) Using other acceptable means of refrigeration.
 - (2) When mechanical refrigeration units are used, the units shall be equipped with automatic controls and shall be capable of maintaining the ambient air in the storage area at temperatures of 45° Fahrenheit (7.2° Centigrade) or less.
 - (3) The dealer shall not be required to provide thermal recorders during shipment.

- (4) Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.
- B. Shipping Time is Greater Than Four Hours.
- (1) When the shipping time is greater than four hours, the dealer shall ship all shellfish in:
- (a) Mechanically refrigerated conveyances which are equipped with automatic controls and capable of maintaining the ambient air in the storage area at temperatures of 45° Fahrenheit (7.2° Centigrade) or less; or
 - (b) Containers with an internal ambient air temperature maintained at or below temperatures of 45° Fahrenheit (7.2° Centigrade) or less.
- (2) Unless the dealer has an approved HACCP plan with an alternate means of monitoring time-temperature, the initial dealer shall assure that a suitable time-temperature recording device accompanies each shipment of shellfish.
- (3) The initial dealer shall note the date and time on the temperature indicating device, if appropriate.
- (4) Each receiving dealer shall write the date and time on the temperature indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened.
- (5) The final receiving dealer shall keep the time-temperature recording chart or other record of time and temperature in his files and shall make it available to the Authority upon request.
- (6) An inoperative temperature-indicating device shall be considered as no recording device.

VII. GENERAL REQUIREMENTS FOR DEALERS

.01 General HACCP Requirements.

A. Hazard Analysis. Every dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur for each kind of shellfish product processed by that dealer and to identify the preventive measures that the dealer can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent dealer would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of shellfish product being processed in the absence of those controls. In the hazard analysis, the dealer shall consider the critical control points listed in Chapters VIII, XIV, X, and XI.

B. HACCP Plan. Every dealer shall have and implement a written HACCP plan. A HACCP plan shall be specific to:

- (1) Each location where shellfish products are processed by that dealer; and
- (2) Each kind of shellfish product processed by the dealer. The plan may group

kinds of shellfish products together, or group kinds of production methods together, if the food safety hazard, critical control points, critical limits, and procedures required to be identified and performed in §.01C. are identical for all shellfish products so grouped or for all production methods so grouped.

C. Contents of the HACCP Plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with §.01A. and that thus must be controlled for each shellfish product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

- (a) Natural toxins;
- (b) Microbiological contamination;
- (c) Chemical contamination;
- (d) Pesticides;
- (e) Drug residues;
- (f) Unapproved use of direct or indirect food or color additives; and
- (g) Physical hazards;

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:

(a) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest. At a minimum, the critical control points shall include those identified in Chapter VIII. 01, Chapter VIV. 01, Chapter X. 01, and Chapter XI. 01, as applicable. As an alternative, the dealer may establish other critical control points which the dealer can demonstrate to the Authority provide equivalent public health protection. If the dealer can demonstrate to the Authority through a hazard analysis that the food safety hazard is not reasonably likely to occur, the critical control point is not required with the exception of receiving which shall always be considered as a critical control point.

(b) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment. As an alternative, the dealer may establish other critical control points which the dealer can demonstrate to the Authority provide equivalent public health protection. If the dealer can demonstrate to the Authority through a hazard analysis that the food safety hazard is not reasonably likely to occur, the critical control point is not required. At a minimum, the critical control points shall include those identified in Chapter VIII. 01A., Chapter VIV. 01A., Chapter X. 01A., and Chapter XI. 01A., as applicable.

(3) List the critical limits that must be met at each of the critical control points. At a minimum, the critical limits shall include those listed in Chapter VIII. 01, Chapter VIV. 01, Chapter X. 01, and Chapter XI.. 01, as applicable. As an alternative the dealer may establish other critical limits which the dealer has demonstrated provide equivalent public health protection with the exception of receiving which shall always be considered as a critical control point. In any case, the critical limits identified in Chapter VIII. 01, Chapter VIV. 01, Chapter X. 01, and Chapter XI.. 01, shall be met as components of good manufacturing

practices.

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.

(5) Include any corrective action plans that have been developed in accordance with §.01F.(2), to be followed in response to deviations from critical limits at critical control points.

(6) Provide for a record keeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and frequency thereof, that the dealer will use in accordance with §.01G.(1).

D. Signing and Dating the HACCP Plan.

(1) The HACCP plan shall be signed and dated, either by the most responsible individual on site at the processing facility or by a higher level official of the dealer. This signature shall signify that the HACCP plan has been accepted for implementation by the dealer.

(2) The HACCP plan shall be signed and dated:

(a) Upon initial acceptance;

(b) Upon any modification; and

(c) Upon verification of the plan in accordance with §.01G.(1)(a).

E. Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with §.02 they need not be included in the HACCP plan, and vice versa.

F. Corrective Actions.

(1) Whenever a deviation from a critical limit occurs, a dealer shall take corrective action either by:

(a) Following a corrective action plan that is appropriate for the particular deviation, or

(b) Following the procedures in §.01F.(3).

(2) Dealers may develop written corrective action plans, which become part of their HACCP plans in accordance with §.01C.(5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(a) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(b) The cause of the deviation is corrected.

(3) When a deviation from a critical limit occurs and the dealer does not have a corrective action plan that is appropriate for that deviation, the dealer shall:

(a) Segregate and hold the affected product, at least until the requirements of §.01F.(3)(b) and (c) are met;

(b) Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with

§.01I.;

(c) Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

(d) Take corrective action, when necessary, to correct the cause of the deviation;

(e) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with §.01I., to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(4) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with §.01G. and the record keeping requirements of §.01H.

G. Verification.

(1) Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(a) A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. These changes may include: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with §.01I. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of §.01C.

(b) Ongoing verification activities including:

- (i) A review of any consumer complaints that have been received by the dealer to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;
- (ii) The calibration of process-monitoring instruments; and
- (iii) At the option of the dealer, the performing of periodic end-product or in-process testing.

(c) A review, including signing and dating, by an individual who has been trained in accordance with § .01I., of the records that document:

- (i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within one (1) week of the day that the records are made;
- (ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with §.01F. This review shall occur within one (1) week of the day that the records are made; and
- (iii) The calibrating of any process monitoring instruments used at critical

control points and the performing of any periodic end-product or in-process testing that is part of the dealer's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a reasonable time after the records are made.

(2) Dealers shall immediately follow the procedures in §.01F. whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(3) The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with §.01G(1)(b)(ii) and (iii) shall be documented in records that are subject to the record keeping requirements of §.01H.

H. Records.

(1) All records required by §.01 and §.02 shall include:

- (a) The name and location of the dealer;
- (b) The date and time of the activity that the record reflects;
- (c) The signature or initials of the person performing the operation; and
- (d) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed.

(2) All records required by §.01 and §.02 shall be retained at the processing facility for at least one (1) year after the date they were prepared in the case of refrigerated products and for at least two (2) years after the date they were prepared in the case of frozen products.

(3) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility for at least two (2) years after their applicability to the product being produced at the facility.

(4) If the processing facility is closed for a prolonged period between seasonal operations, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal operations but shall be immediately returned for official review upon request.

(5) All records required by §.01 and §.02 and HACCP plans required by §.01B. and §.01C. shall be available for official review and copying at reasonable times.

(6) Tags on containers of shellstock are not subject to the requirements of this section unless they are used to fulfill the requirements of Chapter VII. 05.

(7) The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and electronic signatures.

I. Training.

(1) At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to shellfish processing at least equivalent to that received under standardized curriculum recognized as adequate by the Shellstock Shipper Growers

Association (SSGA) or who is otherwise qualified through job experience to perform these functions:

- (a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan that is appropriate for a specific processor, in order to meet the requirements of §.01C.;
 - (b) Reassessing and modifying the HACCP plan in accordance within the corrective action procedures specified in §.01F.(3)(e), and the HACCP plan in accordance with the verification activities specified in § .01G.(1)(a); and
 - (c) Performing the record review required by §.01G.(1)(c).
- (2) Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum as determined by the Authority.
- (3) The trained individual need not be an employee of the dealer.

.02 General Sanitation Requirements.

A. Sanitation Monitoring. Each dealer shall monitor conditions and practices that are both appropriate to the plant and the food being processed with sufficient frequency to ensure, at a minimum, conformance with the requirements specified in Chapter VIII. 02, Chapter XIV. 02, Chapter X. 02, and Chapter XI. 02. The requirements specified in these Sections relate to the following sanitation items:

- (1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice, hereinafter referred to as: Safety of water for processing and ice production;
- (2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product, hereinafter referred to as: Condition and cleanliness of food contact surfaces;
- (3) Prevention of cross contamination from unsanitary objects to food, food packaging materials, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product, hereinafter referred to as: Prevention of cross contamination;
- (4) Maintenance of hand washing, hand sanitizing, and toilet facilities, hereinafter referred to as: Maintenance of hand washing, hand sanitizing and toilet facilities;
- (5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants, hereinafter referred to as: Protection from adulterants;
- (6) Proper labeling, storage, and use of toxic compounds, hereinafter referred to as: Proper labeling, storage, use of toxic compounds;
- (7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces, hereinafter referred to as: Control of employees with adverse health conditions; and
- (8) Exclusion of pests from the food plant, hereinafter referred to as: Exclusion of pests.

While monitoring of those specified conditions and practices [listed in (1) – (8)] that are not appropriate to the plant and the food being processed is not required, compliance with such conditions and practices remains mandatory.

B. Sanitation Monitoring Records. Each dealer shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by §.02A. These records are subject to the requirements of §.01H.

C. Relationship to HACCP Plan. Sanitation controls may be included in the HACCP plan, required by §.01B. However, to the extent that they are monitored in accordance with §.02A. they need not be included in the HACCP plan, and vice versa.

.03 Other Rule Requirements.

Each dealer shall comply with the requirements specified in Chapter VIII. 03, Chapter VIV. 03, Chapter X. 03, and Chapter XI. 03 that are appropriate to the plant and the food being processed. However, monitoring and record keeping for these conditions and practices is not required, unless specifically stated.

.04 Certification Requirements.

A. General.

- (1) No person shall act as a dealer prior to obtaining certification.
- (2) Any person who wants to be a dealer shall:
 - (a) Make application to the Authority for certification;
 - (b) Have and implement a HACCP plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the *Federal Register* of December 18, 1995, except for the requirement for harvester identification on a dealer's tag.
- (3) Each dealer shall have a business address at which inspections of facilities, activities, or equipment can be conducted.

B. Types of Certification.

- (1) Shucker-packer. Any person who shucks shellfish shall be certified as a shucker-packer.
- (2) Repacker.
 - (a) Any person who repacks shucked shellfish shall be certified as a shucker-packer or repacker;
 - (b) Any person who repacks shellstock shall be certified as a shellstock shipper, shucker-packer, or repacker;
 - (c) A repacker shall not shuck shellfish.
- (3) Shellstock Shipper. Any person who ships and receives shellstock in interstate commerce shall be certified as a shellstock shipper, repacker, or shucker-packer.
- (4) Reshipper. Any person who purchases shellstock or shucked shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers or retailers shall be certified as a reshipper.

.05 Shellstock Identification.

A. General.

- (1) The dealer shall keep the harvester's tag affixed to each container of shellstock until the container is:
 - (a) Shipped; or
 - (b) Emptied to wash, grade or pack the shellstock.

(2) When the dealer is also the harvester and s/he elects not to use a harvest tag, the dealer shall affix her/his dealer tag to each container of shellstock prior to shipment.

B. Tags.

(1) The dealers' tags shall:

- (a) Be durable, waterproof and sanctioned by the Authority prior to use; and
- (b) Be at least 2 5/8 inches by 5 1/4 inches (6.7 x 13.3 cm) in size.

(2) The dealer's tag shall contain the following indelible, legible information in the order specified below:

- (a) The dealer's name and address;
- (b) The dealer's certification number as assigned by the Authority and the original shellstock shipper's certification number;
- (c) The date of harvest;
- (d) The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).
- (e) When the shellstock has been transported across state lines and placed in wet storage in a dealer's operation, the statement:

"THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)";

(f) The type and quantity of shellstock; and

(g) The following statement in bold capitalized type on each tag

"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."

(h) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-602.11 of the 2001 Food Code, or an equivalent statement, shall be included on all shellstock:

"RETAILERS, INFORM YOUR CUSTOMERS"

"Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

(3) When both the dealer and harvester tags appear on the container, the dealer's tag is not required to duplicate the information on the harvester's tag.

(4) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in §.05B.

C. Tagging of a Lot of Shellstock During Intermediate Processing.

(1) When the shellstock is removed from the original container, the dealer shall:

- (a) Keep the harvester tag for 90 days;
- (b) Keep track of the growing area and date of harvest for shellstock; and
- (c) Maintain the lot identity of all shellstock during any intermediate stage of processing.

(2) A dealer receiving bulk tagged lots of shellstock must have an intermediate processing plan approved by the Authority to ensure that each lot of shellstock is kept separate and identified in a way which prevents commingling or misidentification.

(3) In order for a dealer to tag a lot container (e.g. a pallet) of shellstock in lieu of meeting the requirement in §.05B. for a harvester or dealer tag on each individual container, the dealer shall have an intermediate processing plan approved by the Authority which establishes the procedures the dealer shall use to tag the lot during the washing, packing or staging of shellfish.

(4) Unless the dealer is included in the Authority's commingling plan under Chapter I. @.01F., the dealer's intermediate processing plan for tagging a lot of shellstock during the intermediate stage of processing shall ensure that each lot of shellstock is separated and identified in a way which prevents commingling or misidentification. The identification shall be provided by:

(a) A harvester's or dealer's tag which meets the requirements of §.05B.; or

(b) A tag for each lot of shellstock which contains the following information:

(i) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest";

(ii) Harvest date;

(iii) Growing area;

(iv) Original dealer certification number; and

(v) Number of individual containers in each lot of shellstock container (e. g. a pallet) after washing, packing or staging has been completed.

(5) When a dealer has an approved intermediate processing plan, the dealer shall tag each lot of shellstock in accordance with the intermediate processing plan while the lot of shellstock is being processed in the plant.

D. Transaction Record. If shellstock are sold in bulk, the dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in §.07B. with the addition of the name of the consignee.

.06 Shucked Shellfish Labeling.

A. Shellfish Labeling.

(1) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section of the regulation. When returnable containers are used, the shipment shall be accompanied by a transaction record containing:

(a) The original shuckers-packer's name and certification number;

(b) The shucking date; and

(c) The quantity of shellfish per container and the total number of containers.

(2) If the dealer uses master shipping cartons, the master cartons are exempt from these labeling requirements when the individual containers within the carton are properly labeled.

(3) At a minimum the dealer shall label each individual package containing fresh or frozen shucked shellfish meat in a legible and indelible form in accordance with CFR 21, Part 101; Part 161, Subpart B (161.30, and 161.136) and the Federal Fair Packaging and Labeling Act.

- (4) The dealer shall assure that each package containing less than 64 fluid ounces of fresh or frozen shellfish shall have:
 - (a) The shucker-packer's or repacker's certification number on the label; and
 - (b) A "SELL BY DATE" which provides a reasonable subsequent shelf-life or the words "BEST IF USED BY" followed by a date when the product would be expected to reach the end of its shelf-life. The date shall consist of the abbreviation for the month and number of the day of the month. For frozen shellfish, the year will be added to the date.
- (5) The dealer shall assure that each package containing more than 64 fluid ounces of fresh or frozen shellfish shall have:
 - (a) The shucker-packer's or repacker's certification number on the label; and
 - (b) A "DATE SHUCKED" which shall:
 - (i) For fresh shellfish, consist of the number of the day of the year or the month and the number of the day of the month;
 - (ii) For frozen shellfish, include the year; and
 - (iii) Appear on the lid and sidewall or bottom of disposable containers.
- (6) If the dealer thaws and repacks frozen shellfish, the dealer shall label the shellfish container as previously frozen.
- (7) The dealer shall provide all label information in a legible and indelible form.
- B. Shucked Shellfish. If the dealer elects to repack shellfish, the dealer shall pack and label all shellfish in accordance with §.06 except that the original date of shucking shall be used in establishing the SELL BY DATE.

.07 Shipping Documents and Records.

- A. Shipping Documents.
 - (1) Each shellfish shipment shall be accompanied by a shipping document.
 - (2) The shipping document shall contain:
 - (a) The name, address, and certification number of the shipping dealer;
 - (b) The name and address of the major consignee; and
 - (c) The kind and quantity of the shellfish product.
 - (3) The receiving dealer shall:
 - (a) Maintain in his files a copy of the completed shipping document; and
 - (b) Make the shipping document available to the Authority upon request.
 - (4) If the shipment is subdivided to different dealers, each receiving dealer shall maintain records sufficient to trace his portion back to the original shipment.
- B. Transaction and Shipping Records.
 - (1) Each dealer shall have a business address at which transaction records are maintained.
 - (2) Each dealer shall maintain complete, accurate and legible records of the Authority's required information in a form authorized by the Authority.
 - (3) Transaction records shall be sufficient to:
 - (a) Document that the shellfish are from a source authorized under this Rule;
 - (b) Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken;
 - (c) Permit a lot (or commingled lots as per Chapter I.@.01. F.) of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, and if possible, the harvester or group of harvesters.

- (4) Purchase and sales shall be recorded:
 - (a) In a permanently bound ledger book; or
 - (b) Using other recording methods acceptable to and authorized by the Authority.
- (5) The transaction records shall be retained:
 - (a) In the case of fresh shellfish, for a minimum of one year; and
 - (b) In the case of frozen shellfish, for at least two years or the shelf life of the product, whichever is longer.
- (6) If computer records are maintained, the Authority shall approve the format and its use.

.08 Wet Storage in Artificial Bodies of Water.

A. General.

- (1) If the dealer chooses to practice wet storage in artificial bodies of water, the dealer shall meet the requirements of Chapter IV. .01, .02 and .03.
- (2) For the purpose of permitting, each wet storage site or operation shall be evaluated annually. The evaluation shall include the operation's plan and operating procedures for an onshore activity as submitted by the dealer.
- (3) Prior to commencing construction, all plans for construction or remodeling of onshore wet storage facilities or operations shall be reviewed and authorized by the Authority.
- (4) The wet storage facility or operation evaluation shall include a review of:
 - (a) The purpose of the wet storage activity, such as holding, conditioning or increasing the salt content of shellstock;
 - (b) Any species specific physiological factors that may affect design criteria; and
 - (c) The plan giving the design of the onshore storage facility, source and quantity of water to be used for wet storage, and details of any water treatment system.

B. Operation Specifications.

- (1) General. Each onshore wet storage operation shall meet the following design, construction, and operating requirements.
 - (a) Effective barriers shall be provided to prevent entry of birds, animals, and vermin into the area.
 - (b) Storage tanks and related plumbing shall be fabricated of safe material and shall be easily cleanable. This requirement shall include:
 - (i) Tanks constructed so as to be easily accessible for cleaning and inspection, self-draining and fabricated from nontoxic, corrosion resistant materials; and
 - (ii) Plumbing designed and installed so that it can be cleaned and sanitized on a regular schedule, as specified in the operating procedures.
 - (c) Storage tank design, dimensions, and construction are such that adequate clearance between shellstock and the tank bottom shall be maintained.
 - (d) Shellstock containers, if used, shall be designed and constructed so that the containers allow the free flow of water to all shellstock within a container.
- (2) Buildings. When a building is used for the wet storage operation:

- (a) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of Chapter VIII.; and
 - (b) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of Chapter VIII.
- (3) Outdoor Tank Operation. When the wet storage operation is outdoors or in a structure other than a building, tank covers shall be used. Tank covers shall:
 - (a) Prevent entry of birds, animals or vermin; and
 - (b) Remain closed while the system is in operation except for periods of tank loading and unloading, or cleaning.
- C. Water Supply.
 - (1) General.
 - (a) Except for wells, the quality of the surface source water prior to treatment shall meet, at a minimum, the bacteriological standards for the restricted classification.
 - (b) Any well used as source water for wet storage shall meet the requirements of Chapter VIII. 02.
 - (c) Except when the source of the water is a growing area in the approved classification, a water supply sampling schedule shall be included in the dealer's operating procedures and water shall be tested according to the schedule.
 - (d) Results of water samples and other tests to determine the suitability of the water supply shall be maintained for at least 2 years.
 - (e) Disinfection or other water treatment such as the addition of salt cannot leave residues unless they are Generally Recognized as Safe (GRAS) or unless they do not interfere with the shellstock's survival, quality or activity during wet storage.
 - (f) Disinfected water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100 ml. for potable water.
 - (g) When the laboratory analysis of a single sample of disinfected water entering the wet storage tanks shows any positive result for the coliform group, daily sampling shall be immediately instituted until the problem is identified and eliminated.
 - (h) When the problem that is causing disinfected water to show positive result for the coliform group is eliminated, the effectiveness of the correction shall be shown on the first operating day following correction through the immediate collection, within a 24 hour period, of a set of three samples of disinfected water and one sample of the source water prior to disinfection.
 - (i) For water that is disinfected by ultra-violet treatment, turbidity shall not exceed 20 nephelometric turbidity units (NTUs) measured in accordance with *Standard Methods for the Examination of Water and Wastewater*, APHA.
 - (j) The disinfection unit(s) for the water supply shall be cleaned and serviced as frequently as necessary to assure effective water treatment.
 - (2) Continuous Flow-through System.
 - (a) If the system is of continuous flow-through design, water from a growing area classified as:

- (i) Approved may be used, without disinfection, in wet storage tanks provided that the near shore water source used for supplying the system meets the approved classification bacteriological criteria at all times that shellstock are being held in wet storage; or
 - (ii) Other than approved may be used if the source water is continuously subjected to disinfection and it is sampled daily following disinfection.
 - (b) When a source classified as other than approved is used, a study shall be required to demonstrate that the disinfection system will consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall:
 - (i) Include five sets of three samples from each disinfection unit collected for five consecutive days at the outlet from the disinfection unit or at the inlet to at least one of the wet storage tanks served by the disinfection system;
 - (ii) Include one sample daily for five consecutive days from the source water prior to disinfection;
 - (iii) Use NSSP recognized methods to analyze the samples to determine coliform levels;
 - (iv) Require all samples of disinfected water to be negative for the coliform group; and
 - (v) Be repeated if any sample of disinfected water during the study is positive for the coliform group.
 - (c) Once sanctioned for use, the water system shall be sampled daily to demonstrate that the disinfected water is negative for the coliform group.
- (3) Recirculating Water System.
- (a) A study shall be required to demonstrate that the disinfection system for the recirculating system will consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall meet the requirements in §C.(2)(b) above.
 - (b) Once sanctioned for use, the recirculating water system shall be sampled weekly to demonstrate that the disinfected water is negative for the coliform group.
 - (c) When make-up water of more than 10 percent of the water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group.
 - (d) When ultra-violet treatment is used as the water disinfectant, each time new ultraviolet bulbs are installed, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group.

D. Shellstock Handling.

- (1) Shellstock shall be thoroughly washed with water from a source authorized by the Authority and culled prior to wet storage in tanks. Due to the adverse effects

of culling on mussel physiology, culling of mussels may be done after wet storage, subject to permission from the Authority.

(2) Unless the dealer is in the Authority's commingling plan under Chapter I.@.01F., different lots of shellstock shall not be commingled during wet storage in tanks. If more than one lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

(3) Bivalve mollusks shall not be mixed with other species in the same tank. Where multiple tank systems use a common water supply system for bivalve mollusks and other species, wet storage water shall be effectively disinfected prior to entering tanks containing the bivalve mollusks.

.09 Post-Harvest Processing.

A dealer may elect to use a process to reduce *Vibrio vulnificus* levels in shellfish.

(A) The dealer shall:

(1) Have a HACCP plan approved by the Authority for the process which includes:

(a) An end point criteria for the process as non-detectable (< 3 MPN/ gram) to be determined by use of the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA *Bacteriological Analytical Manual*, 7th edition, 1992; and

(b) A sampling program to demonstrate that the end point criteria is met.

(2) Package and label all shellfish in accordance with all requirements of this Rule. This includes the labeling all shellfish which has been subjected to the process but which is not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter VII. 05 and VII. 06

(3) Keep records in accordance with Chapter VII. 07.

(B) A dealer who meets the requirements of this section may label product which has been subjected to the reduction process as "Processed to reduce *Vibrio vulnificus* to non-detectable levels".

.10 Processed Products with Labeling Claims for Safety.

All certified dealers processing products with labeling claims for safety shall:

(A) Consult with and adhere to advice from the U. S. Food and Drug Administration for all special labeling claims.

(B) Meet all applicable requirements of this chapter.

(C) For the purposes of refrigeration, if the end product is dead, treat the product as shucked product. If the end product is live it shall be treated as shellstock for the purposes of refrigeration; and,

(D) Shall ensure through controls in their HACCP Plan that claims are met.

VIII. SHUCKING AND PACKING

Requirements for the Authority.

@.01 Heat Shock.

- A. The Authority shall approve the scheduled process for heat shock. The schedule may be developed by the Authority or qualified persons with adequate facilities for conducting the appropriate studies.
- B. The Authority shall assure that the critical factors which may affect the heat shock process have been adequately studied and provided for in establishing the process. The critical factors shall include:
- (1) Type and size of shellfish;
 - (2) Time and temperature of exposure;
 - (3) Type of process;
 - (4) Size of tank, tunnel or retort;
 - (5) Water to shellfish ratios in tanks; and
 - (6) Temperature and pressure monitoring devices.
- C. The Authority shall assure that heat shock process does not:
- (1) Change the physical and organoleptic properties of the species;
 - (2) Kill the shellfish prior to shucking; and
 - (3) Increase microbial deterioration of the shucked shellfish.
- D. The Authority shall retain records covering all aspects of the establishment of the heat shock process.

Requirements for Dealers.

01. Critical Control Points.

- A. Receiving Critical Control Point - Critical Limits. The dealer shall shuck and pack only shellstock which is:
- (1) Obtained from a licensed harvester who has:
 - (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and
 - (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or
 - (2) Obtained from a dealer who has identified the shellstock with a tag on each container or transaction record with each bulk shipment.
- B. Shellstock Storage Critical Control Point -Critical Limits. The dealer shall ensure that:
- (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter VII. 08; and
 - (2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be;
 - (a) Iced; or
 - (b) Placed and stored in a storage area or conveyance maintained at 45° Fahrenheit (7.2° Centigrade) or less; and
 - (c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B(1) or §B(2) for more than 2 hours at points of transfer such as loading docks.
- C. Processing Critical Control Point -Critical Limits. The dealer shall ensure that:
- (1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° Centigrade) or less within three hours of shucking.
 - (2) For shellstock refrigerated prior to shucking, shucked meats are chilled to an

internal temperature of 45° F (7.2° Centigrade) or less within four hours of removal from refrigeration.

(3) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45° Fahrenheit (7.2° Centigrade) or less within two hours after the heat shock process.

D. Shucked Meat Storage Critical Control Point -Critical Limit. The dealer shall store shucked and packed shellfish in covered containers at an ambient air temperature in the storage area of 45° Fahrenheit (7.2° Centigrade) or less.

.02 Sanitation.

A. Safety of Water for Processing and Ice Production.

(1) Water Supply.

(a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations.

(b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority:

(i) Prior to use of the water supply;

(ii) Every six months while the water supply is in use; and

(iii) After the water supply has been repaired and disinfected.

(b) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations.

(2) Ice Production. Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:

(a) Be made on-site from potable water in a commercial ice machine; or

(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency.

(3) Shellstock Washing.

(a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock.

(b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:

(i) Obtain approval for the construction or remodeling of the system from the Authority.

(ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and

(iii) Test bacteriological water quality daily;

(c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed 20 nephelometric turbidity units (NTUs) measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*.

(4) Plumbing and Related Facilities.

(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

- (i) Prevent contamination of water supplies;
- (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source.
- (iii) The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage.

(b) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:

- (i) Is easily accessible for cleaning and inspection;
- (ii) Is self-draining; and
- (iii) Meets the requirements for food contact surfaces.

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guides* (August 1993), U. S. Department of Health and Human Services.

(b) The dealer shall use only equipment and utensils, including approved plasticware and finished product containers which are:

- (i) Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellfish products;
- (ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and
- (iii) Fabricated from food grade materials.

(c) The dealer shall assure that all joints on food contact surfaces:

- (i) Have smooth easily cleanable surfaces; and
- (ii) Are welded.

(d) Shucking blocks shall be provided which are:

- (i) Easily cleanable;
- (ii) Fabricated from safe material;
- (iii) Solid, one piece construction; and
- (iv) Easily removed from the shucking bench, unless the block is an integral part of the bench.

(e) All equipment used in heat shock processing shall meet the requirements of Chapter VIII. 02. B.(1) (a), (b), and (c).

(f) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter VIII. 02. B.(1) (a), (b), and (c).

(2) Cleaning and sanitizing of food contact surfaces.

(a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:

- (i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant;
- (ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; and
- (iii) Wash and rinse equipment and utensils at the end of each day.
- (b) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination.
- (c) Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling.
- (d) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded.
- (e) Shucked shellfish shall be packed in clean containers and stored in a manner which assures their protection from contamination.
- (f) If used, the finger cots or gloves shall be:
 - (i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done;
 - (ii) Sanitized at least twice daily;
 - (iii) Cleaned more often, if necessary;
 - (iv) Properly stored until used; and
 - (v) Maintained in a clean, intact, and sanitary condition.

C. Prevention of Cross Contamination.

(1) Protection of shellfish.

- (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer.
- (b) Shucked shellfish shall be protected from contamination.
- (c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment.
- (d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination.

(2) Employee practices.

- (a) Where the same employee works in both the shucking and packing activities, the employee shall wash his hands thoroughly after entering.
- (b) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:
 - (i) Before starting work;
 - (ii) After each absence from the work station;
 - (iii) After each work interruption; and
 - (iv) Any time when their hands may have become soiled or contaminated.

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

- (1) Handwashing facilities with warm water at a minimum temperature of 110° Fahrenheit (43° Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided.
- (2) Sewage and liquid disposable wastes shall be properly removed from the

facility.

(3) An adequate number of conveniently located toilets shall be provided.

(4) The dealer shall provide each toilet facility with an adequate supply of toilet paper in a suitable holder.

E. Protection from Adulterants.

(1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing.

(2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage.

(3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations.

(4) Protection of ice used in shellfish processing.

(a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination.

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice.

(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed.

F. Proper Labeling, Storage and Use of Toxic Compounds.

(1) Storage of toxic compounds.

(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility.

(b) Each of the following categories of toxic substances shall be stored separately:

(i) Insecticides and rodenticides;

(ii) Detergents, sanitizers, and related cleaning agents; and

(iii) Caustic acids, polishes, and other chemicals.

(c) The dealer shall not store toxic substances above shellfish or food contact surfaces.

(2) Use and labeling of toxic compounds.

(a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues.

(b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations.

(c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions.

G. Control of Employees with Adverse Health Conditions.

(1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The diseases

which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*.

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions.

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities.

.03 Other Rule Requirements.

A. Plants and Grounds.

(1) General.

(a) The physical facilities shall be maintained in good repair.

(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored.

(c) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed.

(2) Flooding:

(a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides.

(b) If facilities are flooded:

(i) Shellfish processing, shucking or repacking activities shall be discontinued until the floodwaters have receded from the building; and the building is cleaned and sanitized.

(ii) Any shellfish coming in contact with the floodwaters while in storage shall be destroyed; or discarded in non-food use.

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities.

(4) Separation of operations.

(a) Facilities for shucking and packing activities shall be separated by use of:

(i) Separate rooms;

(ii) Partitions; or

(iii) Sufficient spacing.

(b) Manufacturing activities which could result in the contamination of the shellfish shall be separated by adequate barriers.

(5) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area.

(6) Plant Interior.

(a) Sanitary conditions shall be maintained throughout the facility.

(b) All dry area floors shall be hard, smooth, easily cleanable; and

(c) All wet area floors used in areas to store shellstock, process food, and

clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:

- (i) Are graded to provide adequate drainage;
- (ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage;
- (iii) Have sealed junctions between floors and walls to render them impervious to water; and

(d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials.

(7) Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

- (a) Rodent attraction and harborage; and
- (b) Inadequate drainage.

B. Plumbing and Related Facilities.

(1) Handwashing facilities shall be provided which are:

- (a) Convenient to work areas;
- (b) Separate from the three compartment sinks used for cleaning equipment and utensils; and
- (c) Directly plumbed to an approved sewage disposal system.

(2) The dealer shall provide at least one handsink in the packing room.

(3) The dealer shall provide at each handwashing facility:

- (a) A supply of hand cleansing soap or detergent;
- (b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air;
- (c) An easily cleanable waste receptacle; and
- (d) Handwashing signs in a language understood by the employees.

(4) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:

- (a) Cold and warm water at all sinks; and
- (b) Handwashing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use.

(5) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:

- (a) Used in shellstock storage;
- (b) Used for food holding units (e. g. refrigeration units);
- (c) Cleaned by hosing, flooding, or similar methods; and
- (d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities.

(6) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations.

(7) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted.

- C. Utilities. Ventilation, heating, or cooling systems shall not create conditions that may cause the shellfish products to become contaminated.
- D. Insect and Vermin Control.
- (1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in her/his facility including:
 - (a) Tight fitting, self-closing doors;
 - (b) Screening of not less than 15 mesh per inch; and
 - (c) Controlled air current.
- E. Disposal of Other Wastes.
- (1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations.
 - (2) Shell and other non-edible materials shall be promptly and effectively removed from the shucking bench or table.
 - (3) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin.
- F. Equipment Construction for Non-food Contact Surfaces.
- (1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced.
 - (2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct:
 - (a) Shucking benches and contiguous walls;
 - (b) Stands or stalls and stools for shucker; and
 - (c) Any non-food contact surfaces in shellfish storage or handling areas.
 - (3) Shucking benches shall drain completely and rapidly, and shall drain away from any shellfish on the benches.
- G. Cleaning Non-food Contact Surfaces.
- (1) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces.
 - (2) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination.
- H. Shellfish Storage and Handling.
- (1) The dealer shall:
 - (a) Assure that shellstock is:
 - (i) Reasonably free of sediment; and
 - (ii) Culled;
 - (b) Completely empty shucking buckets at the packing room so that no overage is returned to the shucker;
 - (c) Inspect incoming shipments and shall reject dead or inadequately protected shellstock;
 - (d) Not allow the use of dip buckets for hand or knife rinsing;
 - (e) Not have on the premises any usable containers or container covers

bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source;

(f) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161§ 130;

(g) Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room;

(h) Conduct packing activities so as to conform to applicable food additive regulations;

(i) Store packaged shellfish, if they are to be frozen, at an ambient temperature of 0° Fahrenheit (-17.8° Centigrade) or less; and frozen solid within twelve hours following the initiation of freezing;

(j) Not commingle shellstock during shucking unless the dealer is included in the Authority's commingling plan.

I. Heat Shock. A dealer may elect to use heat shock to prepare shellstock for shucking.

(1) The dealer shall:

(a) Post the schedule for the heat shock process in a conspicuous location; and

(b) Make sure all responsible persons are familiar with the requirements.

(c) Cool all hot dipped shellstock immediately after the heat shock process.

This cooling shall be accomplished by:

(i) Dipping in a ice bath; or

(ii) Use of flowing potable water.

(2) If a heat shock water tank is used, the dealer shall completely drain and flush the tank at three-hour intervals or less so that all mud and debris which have accumulated in the dip tank are eliminated.

J. Personnel. Any employee handling shucked shellfish shall be required to:

(1) Wear effective hair restraints;

(2) Remove any hand jewelry that cannot be sanitized or secured;

(3) Wear finger cots or gloves if jewelry cannot be removed;

(4) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean;

(5) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:

(i) Store clothing or other personal belongings;

(ii) Eat or drink;

(iii) Spit; and

(iv) Use tobacco in any form.

K. Supervision.

(1) A reliable, competent individual shall be designated to supervise general plant management and activities.

(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces.

(3) All supervisors shall be:

- (a) Trained in proper food handling techniques and food protection principles; and
- (b) Knowledgeable of personal hygiene and sanitary practices.
- (4) The dealer shall require:
 - (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing.
 - (b) Supervisors to assure that proper sanitary practices are implemented, including:
 - (i) Plant and equipment clean-up;
 - (ii) Rapid product handling; and
 - (iii) Shellfish protection from contamination.
 - (c) Employees:
 - (i) to be trained in proper food handling and personal hygiene practices, and
 - (ii) to report any symptoms of illness to their supervisor.

VIV. REPACKING OF SHUCKED SHELLFISH

.01 Critical Control Points.

- A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which:
 - (1) Originated from a dealer; and
 - (2) Are identified with a label as outlined in Chapter VII.06.
- B. Processing Critical Control Point - Critical Limits. The dealer shall ensure that repacked shellfish are:
 - (1) Maintained at an internal temperature of 45° Fahrenheit (7.2° Centigrade) or less; and
 - (2) Maintained at a temperature less than 45° Fahrenheit (7.2° Centigrade) in any portion of frozen shellfish thawed for repacking.
- C. Shucked Meat Storage Critical Control Point -Critical Limit. The dealer shall store repacked shellfish in covered containers at an ambient air temperature of 45° Fahrenheit (7.2° Centigrade) or less.

02. Sanitation.

- A. Safety of Water for Processing and Ice Production.
 - (1) Water Supply.
 - (a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations.
 - (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority:

- (i) Prior to use of the water supply;
 - (ii) Every six months while the water supply is in use; and
 - (iii) After any water supply has been repaired and disinfected.
- (c) The dealer shall assure that any steam used in food processing or that comes in contact with food surfaces is free from any additives or deleterious substances consistent with federal and state laws and regulations.
- (2) Ice Production. Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:
 - (a) Be made on-site from potable water in a commercial ice machine; or
 - (b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency.
- (3) Plumbing and Related Facilities.
 - (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
 - (i) Prevent contamination of water supplies;
 - (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage.
- B. Condition and Cleanliness of Food Contact Surfaces.
 - (1) Equipment and utensil construction for food contact surfaces.
 - (a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guides* (August 1993), U. S. Department of Health and Human Services.
 - (b) The dealer shall use only equipment and utensils, including approved plastic ware which are:
 - (i) Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; and
 - (ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and
 - (iii) Fabricated from food grade materials.
 - (c) The dealer shall assure that all joints on food contact surfaces:
 - (i) Have smooth easily cleanable surfaces; and
 - (ii) Are welded.
 - (d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter VIII. 02. B.(1)(a), (b), and (c).
 - (2) Cleaning and sanitizing of food contact surfaces.
 - (a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:
 - (i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant;

- (ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; and
 - (iii) Wash and rinse equipment and utensils at the end of each day.
- (3) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded.
- (4) Shucked shellfish shall be repacked in clean containers:
 - (a) Fabricated from food grade materials; and
 - (b) Stored in a manner which assures their protection from contamination.
- (5) If used, the finger cots or gloves shall be:
 - (i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done;
 - (ii) Sanitized at least twice daily;
 - (iii) Cleaned more often, if necessary;
 - (iv) Properly stored until used; and
 - (v) Maintained in a clean, intact, and sanitary conditions.
- C. Prevention of Cross Contamination.
 - (1) Protection of shellfish.
 - (a) Shucked shellfish shall be protected from contamination.
 - (b) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination.
 - (2) Employee practices.
 - (a) The dealer shall assure that all employees working in direct contact with shellfish processing activities or food contact surfaces maintain a high level of personal hygiene and cleanliness.
 - (b) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:
 - (i) Before starting work;
 - (ii) After each absence from the work station;
 - (iii) After each work interruption; and
 - (iv) Any time when their hands may have become soiled or contaminated.
- D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
 - (1) Handwashing facilities with warm water at a minimum temperature of 110 Fahrenheit (43 Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided.
 - (2) Sewage and liquid disposable wastes shall be properly removed from the facility.
 - (3) An adequate number of conveniently located, toilets shall be provided.
 - (4) The dealer shall provide each toilet facility with an adequate supply of toilet paper in a suitable holder.
- E. Protection from Adulterants.
 - (1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing.
 - (2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage.

(3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations.

(4) Protection of ice used in shellfish processing.

(a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination.

(b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice.

(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed.

F. Proper Labeling, Storage and Use of Toxic Compounds.

(1) Storage of toxic compounds.

(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility.

(b) Each of the following categories of toxic substances shall be stored separately:

(i) Insecticides and rodenticides;

(ii) Detergents, sanitizers, and related cleaning agents; and

(iii) Caustic acids, polishes, and other chemicals.

(c) The dealer shall not store toxic substances above shellfish or food contact surfaces.

(2) Use and labeling of toxic compounds.

(a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or repackaging materials with residues.

(b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations.

(c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions.

G. Control of Employees with Adverse Health Conditions.

(1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*.

(2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions.

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests which may be a source of shellfish contamination are excluded from her/his facility and her/his activities.

03. Other Rule Requirements.

A. Plants and Grounds.

(1) General.

(a) The physical facilities shall be maintained in good repair.

(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored.

(c) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed.

(2) Flooding:

(a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides.

(b) If facilities are flooded:

(i) Shellfish processing, shucking or repacking activities shall be discontinued until the floodwaters have receded from the building; and the building is cleaned and sanitized.

(ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use.

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities.

(4) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area.

(5) Plant Interior.

(a) Sanitary conditions shall be maintained throughout the facility.

(b) All dry area floors shall be hard, smooth, easily cleanable and;

(c) All wet area floors used in areas to process food and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:

(i) Are graded to provide adequate drainage;

(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage;

(iii) Have sealed junctions between floors and walls to render them impervious to water; and

(d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or shall be constructed of easily cleanable, corrosion resistant, impervious and packaged materials.

(6) Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

(a) Rodent attraction and harborage; and

(b) Inadequate drainage.

B. Plumbing and Related Facilities.

(1) Handwashing facilities shall be provided which are:

- (a) Convenient to work areas;
 - (b) Separate from the three compartment sinks used for cleaning equipment and utensils; and
 - (c) Directly plumbed to an approved sewage disposal system.
- (2) The dealer shall provide at least one handsink in the packing room.
- (3) The dealer shall provide at each handwashing facility:
 - (a) A supply of hand cleansing soap or detergent;
 - (b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air;
 - (c) An easily cleanable waste receptacle; and
 - (d) Handwashing signs in a language understood by the employees.
- (4) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:
 - (a) Cold and warm water at all sinks; and
 - (b) Handwashing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use.
- (5) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
 - (a) Used for food holding units (e. g. refrigeration units);
 - (b) Cleaned by hosing, flooding, or similar methods; and
 - (c) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities.
- (6) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations.
- (7) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted.
- C. Utilities. Ventilation, heating, or cooling systems shall not create conditions that may cause the shellfish products to become contaminated.
- D. Insect and Vermin Control.
 - (1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:
 - (a) Tight fitting, self-closing doors;
 - (b) Screening of not less than 15 mesh per inch; and
 - (c) Controlled air currents.
- E. Disposal of Other Wastes.
 - (1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations.
 - (2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin.
- F. Equipment Construction for Non-food Contact Surfaces.
 - (1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized,

maintained, or replaced; and

(2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellfish storage or handling areas.

G. Cleaning Non-food Contact Surfaces.

(1) Cleaning activities for equipment and utensils shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces.

(2) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination.

H. Shellfish Storage and Handling.

(1) The dealer shall:

(a) Not commingle shellfish from different lots;

(b) Repack shucked shellfish meats only into containers labeled with the authorized certification number;

(c) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source;

(d) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161§ 130.

(e) Thoroughly drain, clean as necessary, and repack shucked shellfish meats promptly;

(f) Conduct repacking activities so as to conform to applicable food additive regulations;

(g) Store packaged shellfish, if they are to be frozen, at an ambient temperature of 0° Fahrenheit (-17.8° Centigrade) or less and frozen solid within twelve hours following the initiation of freezing.

I. Heat Shock. N/A

J. Personnel. Any employee handling shucked shellfish shall be required to:

(1) Wear effective hair restraints;

(2) Remove any hand jewelry that cannot be sanitized or secured;

(3) Wear finger cots or gloves if jewelry cannot be removed;

(4) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean;

(5) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:

(i) Store clothing or other personal belongings;

(ii) Eat or drink;

(iii) Spit; and

(iv) Use tobacco in any form.

K. Supervision.

(1) A reliable, competent individual shall be designated to supervise general plant management and activities.

- (2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces.
- (3) All supervisors shall be:
 - (a) Trained in proper food handling techniques and food protection principles; and
 - (b) Knowledgeable of personal hygiene and sanitary practices.
- (4) The dealer shall require:
 - (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing;
 - (b) Supervisors to assure that proper sanitary practices are implemented, including:
 - (i) Plant and equipment cleanup;
 - (ii) Rapid product handling; and
 - (iii) Shellfish protection from contamination.
 - (c) Employees:
 - (i) to be trained in proper food handling and personal hygiene practices; and
 - (ii) to report any symptoms of illness to their supervisor.

X. SHELLSTOCK SHIPPING

Exceptions. Shellstock Shippers are not required to pack shellstock in a building that complies with Sections .02 and .03 of this chapter when the Authority has determined that a shellstock shipper's practices and conditions do not warrant requiring shellstock to be packed in a building.

01. Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. The dealer shall ship or repack only shellstock which is:

- (1) Obtained from a licensed harvester who has:
 - (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and
 - (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or
- (2) Obtained from a dealer who has identified the shellstock with a tag on each container.

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:

- (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter VII. 08; and
- (2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:

- (a) Iced; or
 - (b) Placed in a storage area or conveyance maintained at 45° Fahrenheit (7.2° Centigrade) or less; and
 - (c) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §B(1) or §B(2) for more than 2 hours at points of transfer such as loading docks.
- C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store repacked shellfish in covered containers at an ambient air temperature of 45° Fahrenheit (7.2° Centigrade) or less.

02. Sanitation.

A. Safety of Water for Processing and Ice Production.

(1) Water Supply.

- (a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations.
- (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority:
 - (i) Prior to use of the water supply;
 - (ii) Every six months while the water supply is in use; and
 - (iii) After any water supply has been repaired and disinfected.
- (c) The dealer shall assure that any steam used in food processing or that comes in contact with food surfaces is free from any additives or deleterious substances consistent with federal and state laws and regulations.

(2) Ice Production. Any ice used in the processing, storage, or transport of shellstock shall:

- (a) Be made on-site from potable water in a commercial ice machine; or
- (b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency.

(3) Shellstock Washing.

- (a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock.
- (b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:
 - (i) Obtain approval for the construction or remodeling of the system from the Authority;
 - (ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and
 - (iii) Test bacteriological water quality daily.
- (c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed 20 nephelometric turbidity units (NTUs) measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*.

(4) Plumbing and Related Facilities.

(a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

- (i) Prevent contamination of water supplies;
- (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage.

(b) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:

- (i) Is easily accessible for cleaning and inspection;
- (ii) Is self-draining; and
- (iii) Meets the requirements for food contact surfaces.

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guides* (August 1993), U. S. Department of Health and Human Services.

(b) The dealer shall use only equipment and utensils, including approved plastic ware which are:

- (i) Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellstock;
- (ii) Free from exposed screws, bolts or rivet heads on food contact surfaces and
- (iii) Fabricated from food grade materials.

(c) The dealer shall assure that all joints on food contact surfaces:

- (i) Have smooth easily cleanable surfaces; and
- (ii) Are welded.

(d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter VIII. 02B.(1) (a), (b), and (c).

(2) Cleaning and Sanitizing of Food Contact Surfaces.

(a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellstock and other food contact surfaces. The dealer shall:

- (i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant;
- (ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; and
- (iii) Wash and rinse equipment and utensils at the end of each day.

(b) Containers which may have become contaminated during storage shall be washed, rinsed and sanitized prior to use or shall be discarded.

- (3) If used, the finger cots or gloves shall be:
 - (a) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done;
 - (b) Sanitized at least twice daily;
 - (c) Cleaned more often, if necessary;
 - (d) Properly stored until used; and
 - (e) Maintained in a clean, intact, and sanitary conditions.

C. Prevention of Cross Contamination.

(1) Protection of Shellfish.

- (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer.
- (b) Shucked shellfish shall be protected from contamination.
- (c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment.
- (d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination.

(2) Employee practices.

- (a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:
 - (i) Before starting work;
 - (ii) After each absence from the work station;
 - (iii) After each work interruption; and
 - (iv) Any time when their hands may have become soiled or contaminated.

D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.

- (1) Handwashing facilities with warm water at a minimum temperature of 110° Fahrenheit (43° Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided.
- (2) Sewage and liquid disposable wastes shall be properly removed from the facility.
- (3) An adequate number of conveniently located, toilets shall be provided.
- (4) The dealer shall provide each toilet facility with an adequate supply of toilet paper in a suitable holder.

E. Protection from Adulterants.

- (1) Shellstock shall be protected from contamination while being transferred from one point to another during handling and processing;
- (2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellstock are exposed shall be of the safety type or protected to prevent food contamination in case of breakage.
- (3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations.
- (4) Shellstock shall be packed in clean containers.
- (5) Protection of ice used in shellstock processing.
 - (a) Any ice which is not made on site in the shellstock processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination.

- (b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice.
 - (6) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed.
- F. Proper Labeling, Storage and Use of Toxic Compounds.
 - (1) Storage of toxic compounds.
 - (a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility.
 - (b) Each of the following categories of toxic substances shall be stored separately:
 - (i) Insecticides and rodenticides;
 - (ii) Detergents, sanitizers, and related cleaning agents; and
 - (iii) Caustic acids, polishes, and other chemicals.
 - (c) The dealer shall not store toxic substances above shellfish or food contact surfaces.
 - (2) Use and labeling of toxic compounds.
 - (a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellstock or packaging materials with residues.
 - (b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations.
 - (c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions.
- G. Control of Employees with Adverse Health Conditions.
 - (1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellstock or with food contact surfaces. The diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*.
 - (2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions.
- H. Exclusion of Pests. The dealer shall operate his facility to assure that pests which may be a source of shellstock contamination are excluded from his facility and his activities.

.03 Other Rule Requirements.

- A. Plants and Grounds.
 - (1) General.
 - (a) The physical facilities shall be maintained in good repair.
 - (b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellstock are stored, handled, processed, or packaged or

food handling equipment, utensils, and packaging materials are cleaned or stored.

(2) Flooding:

(a) Facilities in which shellstock are stored, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides.

(b) If facilities are flooded:

(i) Shellstock processing, repacking or shipping activities shall be discontinued until the floodwaters have receded from the building; and the building is cleaned and sanitized.

(ii) Any shellstock coming in contact with the floodwaters while in storage shall be destroyed; or discarded in non-food use.

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities.

(4) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area.

(5) Plant Interior.

(a) Sanitary conditions shall be maintained throughout the facility;

(b) All dry area floors shall be hard, smooth, easily cleanable and in good repair; and

(c) All wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:

(i) Are graded to provide adequate drainage;

(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage;

(iii) Have sealed junctions between floors and walls to render them impervious to water; and

(d) Walls and Ceilings. Interior surfaces of rooms where shellstock are stored, handled, processed, or shall be constructed of easily cleanable, corrosion resistant, impervious packaged materials.

(6) Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellstock contamination. These conditions may include:

(a) Rodent attraction and harborage; and

(a) Inadequate drainage.

B. Plumbing and Related Facilities.

(1) Handwashing facilities shall be provided which are:

(a) Convenient to work areas;

(b) Separate from the three compartment sinks used for cleaning equipment and utensils; and

(c) Directly plumbed to an approved sewage disposal system.

(2) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:

- (a) Cold and warm water at all sinks; and
 - (b) Handwashing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use;
 - (3) Handwashing facilities: The dealer shall provide at each handwashing facility:
 - (a) A supply of hand cleansing soap or detergent;
 - (b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air;
 - (c) An easily cleanable waste receptacle; and
 - (d) Handwashing signs in a language understood by the employees;
 - (4) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
 - (a) Used in shellstock storage;
 - (b) Used for food holding units (e. g. refrigeration units);
 - (c) Cleaned by hosing, flooding, or similar methods; and
 - (d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities;
 - (5) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations;
 - (6) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted.
- C. Utilities. Ventilation, heating, or cooling systems shall not create conditions that may cause the shellfish products to become contaminated.
- D. Insect and Vermin Control.
- (1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:
 - (a) Tight fitting, self-closing doors;
 - (b) Screening of not less than 15 mesh per inch; and
 - (c) Controlled air currents.
- E. Disposal of Other Waste
- (1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations.
 - (2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin.
- F. Equipment Construction for Non-food Contact Surfaces.
- (1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced; and
 - (2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellstock storage or handling areas.
- G. Cleaning of Non-food Contact Surfaces.
- (1) Cleaning and sanitizing activities for equipment and utensils shall be conducted in a manner and at a frequency appropriate to prevent contamination

of shellstock and food contact surfaces.

(2) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination.

H. Shellstock Storage and Handling.

(1) The dealer shall:

(a) Assure that shellstock is:

- (i) Alive;
- (ii) Reasonably free of sediment; and
- (iii) Culled.

(b) Not commingle shellstock during repacking unless the dealer is included in the Authority's commingling plan.

(2) The dealer shall inspect incoming shipments and shall reject dead or inadequately protected shellstock.

(3) A dealer whose activity consists of trucks or docking facilities only shall:

- (a) Have a permanent business address at which records are maintained and inspections can be performed; and
- (b) Not repack shellstock.

(4) A dealer who stores or repacks shellstock shall have:

- (a) His/her own facility for proper storage or repacking of shellstock; or
- (b) Arrangements with a facility approved by the Authority for the storage or repacking of shellstock.

I. Heat Shock – N/ A

J. Personnel. In any area where shellstock are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:

- (1) Store clothing or other personal belongs;
- (2) Eat or drink;
- (3) Spit; and
- (4) Use tobacco in any form.

K. Supervision.

(1) A reliable, competent individual shall be designated to supervise general plant management and activities.

(2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellstock or food contact surfaces.

(3) All supervisors shall be:

- (a) Trained in proper food handling techniques and food protection principles; and
- (b) Knowledgeable of personal hygiene and sanitary practices.

(4) The dealer shall require:

- (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing.
- (b) Supervisors to assure that proper sanitary practices are implemented, including:

- (i) Plant and equipment cleanup;
 - (ii) Rapid product handling; and
 - (iii) Shellfish protection from contamination.
- (c) Employees:
 - (i) to be trained in proper food handling and personal hygiene practices, and
 - (ii) to report any symptoms of illness to their supervisor.

XI. RESHIPPING

Exceptions. Reshippers are not required to comply with the building requirements in Sections .02 and .03 of this chapter when the Authority has determined that a reshipper's practices and conditions do not warrant requiring a building.

.01 Critical Control Points.

- A. Receiving Critical Control Point - Critical Limits. The dealer shall reship only shellfish which:
 - (1) Originated from a dealer;
 - (2) Are identified with a tag as outlined in Chapter VII.05 or a label as outlined in Chapter VII. 06.
- B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
 - (1) Iced; or
 - (2) Placed in a storage area or conveyance maintained at 45° Fahrenheit (7.2° Centigrade) or less; and
 - (3) Not permitted to remain without ice, mechanical refrigeration, or other approved means of refrigeration for more than 2 hours at points of transfer such as loading docks.
- C. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked shellfish at a temperature of 45° Fahrenheit (7.2° Centigrade) or less.

02. Sanitation.

- A. Safety of Water for Processing and Ice Production.
 - (1) Water Supply.
 - (a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations.
 - (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority:

- (i) Prior to use of the water supply;
 - (ii) Every six months while the water supply is in use; and
 - (iii) After any water supply has been repaired and disinfected.
- (2) Ice Production. Any ice used in the storage or transport of shellstock or shucked shellfish shall:
 - (a) Be made on-site from potable water in a commercial ice machine; or
 - (b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency.
- (3) Plumbing and Related Facilities.
 - (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
 - (i) Prevent contamination of water supplies;
 - (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source . The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage.
- B. Condition and Cleanliness of Food Contact Surfaces. Equipment and utensil construction for food contact surfaces. All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter VIII. 02B.(1) (a), (b), and (c).
- C. Prevention of Cross Contamination.
 - (1) Protection of shellfish.
 - (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer.
 - (b) Shucked shellfish shall be protected from contamination.
 - (c) Equipment shall be stored in a manner to prevent splash, dust, and contamination.
 - (2) Employee practices. The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:
 - (a) Before starting work;
 - (b) After each absence from the work station;
 - (c) After each work interruption; and
 - (d) Any time when their hands may have become soiled or contaminated.
- D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
 - (1) Handwashing facilities with warm water at a minimum temperature of 110° Fahrenheit (43° Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided.
 - (2) Sewage and liquid disposable wastes shall be properly removed from the facility.
 - (3) An adequate number of conveniently located, toilets shall be provided.
 - (4) The dealer shall provide each toilet facility with an adequate supply of toilet paper in a suitable holder.
- E. Protection from Adulterants.
 - (1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing.

- (2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage.
- (3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations.
- (4) Protection of ice used in shellfish reshipping.
 - (a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination.
 - (b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice.
- (5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed.

F. Proper Labeling, Storage and Use of Toxic Compounds.

- (1) Storage of toxic compounds.
 - (a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility.
 - (b) Each of the following categories of toxic substances shall be stored separately:
 - (i) Insecticides and rodenticides;
 - (ii) Detergents, sanitizers, and related cleaning agents; and
 - (iii) Caustic acids, polishes, and other chemicals.
 - (c) The dealer shall not store toxic substances above shellfish.
- (2) Use and labeling of toxic compounds.
 - (a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues.
 - (b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations.
 - (c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions.

G. Control of Employees with Adverse Health Conditions.

- (1) The dealer shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*.
- (2) If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions.

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests which may be a source of shellfish contamination are excluded from his facility and his activities.

.03 Other Rule Requirements.

A. Plants and Grounds.

(1) General.

(a) The physical facilities shall be maintained in good repair.

(b) Animals or unauthorized persons shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored.

(2) Flooding:

(a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides.

(b) If facilities are flooded:

(i) Shellfish processing, shucking, repacking, or reshipping activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized

(ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use.

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities.

(4) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area.

(5) Plant Interior.

(a) Sanitary conditions shall be maintained throughout the facility.

(b) All dry area floors shall be hard, smooth, easily cleanable; and

(c) All wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:

(i) Are graded to provide adequate drainage;

(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage;

(iii) Have sealed junctions between floors and walls to render them impervious to water; and

(iv) Are maintained in good repair.

(d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials.

(6) Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

(a) Rodent attraction and harborage; and

(b) Inadequate drainage.

B. Plumbing and Related Facilities.

- (1) Handwashing facilities shall be provided which are:
 - (a) Convenient to work areas;
 - (b) Separate from the three compartment sinks used for cleaning equipment and utensils; and
 - (c) Directly plumbed to an approved sewage disposal system.
- (2) All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:
 - (a) Cold and warm water at all sinks; and
 - (b) Handwashing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use;
- (3) The dealer shall provide at each handwashing facility:
 - (a) A supply of hand cleansing soap or detergent;
 - (b) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air;
 - (c) An easily cleanable waste receptacle; and
 - (d) Handwashing signs in a language understood by the employees;
- (4) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
 - (a) Used in shellstock storage;
 - (b) Used for food holding units (e. g. refrigeration units);
 - (c) Cleaned by hosing, flooding, or similar methods; and
 - (d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities.
- (5) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations;
- (6) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted.

C. Utilities. Ventilation, heating, or cooling systems shall not create conditions that may cause the shellfish products to become contaminated.

D. Insect and Vermin Control.

- (1) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:
 - (a) Tight fitting, self-closing doors;
 - (b) Screening of not less than 15 mesh per inch; and
 - (c) Controlled air currents;

E. Disposal of Other Wastes.

- (1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations.
- (2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin.

F. Equipment Construction for Non-food Contact Surfaces.

- (1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced.
- (2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellfish storage or handling areas.

G. Cleaning Non-food Contact Surfaces.

- (1) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces.
- (2) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination.

H. Shellfish Storage and Handling

- (1) The dealer shall:
 - (a) Buy shellfish only from sources certified by the Authority or listed in the ICSSL; and
 - (b) Add his name and certification number to the package.
- (2) The dealer shall not:
 - (a) Commingle, sort, or repack shellstock or shucked shellfish; or
 - (b) Remove or alter any existing tag or label.
- (3) A dealer whose activity consists of trucks only shall:
 - (a) Have his own facility for the storage of shellfish; or
 - (b) Have arrangements with a facility approved by the Authority for the storage of shellfish; and
 - (c) Have a permanent business address at which records are maintained and inspections can be performed.

I. Heat Shock – N/ A

J. Personnel. In any area where shellfish are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:

- (1) Store clothing or other personal belongs;
- (2) Eat or drink;
- (3) Spit; and
- (4) Use tobacco in any form.

K. Supervision.

- (1) A reliable, competent individual shall be designated to supervise general plant management and activities.
- (2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces.
- (3) All supervisors shall be:
 - (a) Trained in proper food handling techniques and food protection principles; and
 - (b) Knowledgeable of personal hygiene and sanitary practices.
- (4) The dealer shall require:

- (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing.
- (b) Supervisors to assure that proper sanitary practices are implemented, including:
 - (i) Plant and equipment cleanup;
 - (ii) Rapid product handling; and
 - (iii) Shellfish protection from contamination.
- (c) Employees:
 - (i) to be trained in proper food handling and personal hygiene practices.
 - (ii) to report any symptoms of illness to their supervisor.